

Calendar No. 202118TH CONGRESS
1ST SESSION**S. 2333**

To reauthorize certain programs under the Public Health Service Act with respect to public health security and all-hazards preparedness and response, and for other purposes.

IN THE SENATE OF THE UNITED STATES

JULY 18, 2023

Mr. CASEY (for himself, Mr. ROMNEY, Mr. SANDERS, and Mr. CASSIDY) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

SEPTEMBER 6, 2023

Reported by Mr. SANDERS, with an amendment

[Strike out all after the enacting clause and insert the part printed in italic]

A BILL

To reauthorize certain programs under the Public Health Service Act with respect to public health security and all-hazards preparedness and response, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

1 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

2 (a) **SHORT TITLE.**—This Act may be cited as the
 3 “Pandemic and All-Hazards Preparedness and Response
 4 Act”.

5 (b) **TABLE OF CONTENTS.**—The table of contents for
 6 this Act is as follows:

Sec. 1. Short title; table of contents.

TITLE I—STATE AND LOCAL READINESS AND RESPONSE

Sec. 101. Temporary reassignment of State and local personnel during a public health emergency.

Sec. 102. Public Health Emergency Preparedness program.

Sec. 103. Improving and enhancing participation of EMS organizations in the hospital preparedness program.

Sec. 104. Improving medical readiness and response capabilities.

Sec. 105. Pilot program to support State medical stockpiles.

Sec. 106. Enhancing domestic wastewater surveillance for pathogen detection.

Sec. 107. Reauthorization of Mosquito Abatement for Safety and Health program.

TITLE II—FEDERAL PLANNING AND COORDINATION

Sec. 201. All-Hazards Emergency Preparedness and Response.

Sec. 202. National Health Security Strategy.

Sec. 203. Improving development and distribution of diagnostic tests.

Sec. 204. Pilot program for public health data availability.

Sec. 205. Combating antimicrobial resistance.

Sec. 206. Strategic National Stockpile and material threats.

Sec. 207. Medical countermeasures for viral threats with pandemic potential.

Sec. 208. Public Health Emergency Medical Countermeasures Enterprise.

Sec. 209. Strengthening public health communication.

Sec. 210. Fellowship and training programs.

Sec. 211. Assessment of COVID-19 mitigation policies.

TITLE III—ADDRESSING THE NEEDS OF ALL INDIVIDUALS

Sec. 301. Transition of certain countermeasures between compensation programs.

Sec. 302. Accelerating injury compensation program administration and ensuring program integrity.

Sec. 303. Compensation for injuries relating to the public health emergency caused by SARS-CoV-2.

Sec. 304. Review of regulations.

Sec. 305. Supporting individuals with disabilities, older adults, and other at-risk individuals during emergency responses.

Sec. 306. National advisory committees.

Sec. 307. Research and coordination of activities concerning the long-term health effects of SARS-CoV-2 infection.

Sec. 308. National Academies study on prizes.

TITLE IV—STRENGTHENING BIOSECURITY

- Sec. 401. Treatment of genetic variants and synthetic products of select agents and toxins.
- Sec. 402. Establishment of no-fault reporting system.
- Sec. 403. Evaluation of the Federal Select Agent Program and related policies.
- Sec. 404. Supporting research and laboratory surge capacity.
- Sec. 405. Gene synthesis.
- Sec. 406. Limitation related to countries of concern conducting certain research.
- Sec. 407. Assessment of artificial intelligence threats to health security.

TITLE V—PREVENTING DRUG SHORTAGES

- Sec. 501. Improving notification procedures in case of increased demand for critical drugs.
- Sec. 502. Reporting on supply chains.
- Sec. 503. Reporting on use of new authorities and requirements with respect to drug shortages.

TITLE VI—ADDITIONAL REAUTHORIZATIONS AND TECHNICAL AMENDMENTS

- Sec. 601. Medical countermeasure priority review voucher.
- Sec. 602. Epidemic Intelligence Service loan repayment program.
- Sec. 603. Vaccine tracking and distribution.
- Sec. 604. Regional health care emergency preparedness and response systems.
- Sec. 605. Emergency system for advance registration of volunteer health professional.
- Sec. 606. Limited antitrust exemption.
- Sec. 607. Trauma care.
- Sec. 608. Military and civilian partnership for trauma readiness.
- Sec. 609. National Disaster Medical System.
- Sec. 610. Volunteer Medical Reserve Corps.
- Sec. 611. Epidemiology-laboratory capacity grants.
- Sec. 612. Veterans Affairs.
- Sec. 613. Technical amendments.

1 **TITLE I—STATE AND LOCAL**
 2 **READINESS AND RESPONSE**

3 **SEC. 101. TEMPORARY REASSIGNMENT OF STATE AND**
 4 **LOCAL PERSONNEL DURING A PUBLIC**
 5 **HEALTH EMERGENCY.**

6 Section 319(e) of the Public Health Service Act (42
 7 U.S.C. 247d(e)) is amended—

8 (1) in paragraph (1), by striking “such Gov-
 9 ernor or tribal organization’s designee” and insert-

1 ing “the designee of the Governor or Tribal organi-
 2 zation, or the State or Tribal health official”;

3 (2) in paragraph (2)(B)—

4 (A) in the matter preceding clause (i), by
 5 striking “tribal organization” and inserting
 6 “Tribal organization, or the State or Tribal
 7 health official”; and

8 (B) in clause (v), by striking “tribal orga-
 9 nization” and inserting “Tribal organization or
 10 State or Tribal health official”;

11 (3) in paragraph (6)—

12 (A) in the matter preceding subparagraph
 13 (A)—

14 (i) by striking “Reauthorization Act
 15 of 2013” and inserting “and Response
 16 Act”; and

17 (ii) by striking “appropriate commit-
 18 tees of the Congress” and inserting “Com-
 19 mittee on Health, Education, Labor, and
 20 Pensions of the Senate and the Committee
 21 on Energy and Commerce of the House of
 22 Representatives”; and

23 (B) in subparagraph (A), by inserting “,
 24 including requests from State or Tribal health
 25 officials” before the semicolon;

1 (i) in the paragraph heading, by strik-
2 ing “INFLUENZA” and inserting “RE-
3 SPONSE”; and

4 (ii) in subparagraph (A)—

5 (I) by striking “to pandemic in-
6 fluenza” and inserting “to a pathogen
7 causing a pandemic, including pan-
8 demic influenza”; and

9 (II) by striking “such pandemic
10 influenza” and inserting “such pan-
11 demic response”;

12 (C) in paragraph (5)—

13 (i) in the paragraph heading, by strik-
14 ing “INFLUENZA” and inserting “PAN-
15 DEMIC RESPONSE”;

16 (ii) in the matter preceding subpara-
17 graph (A), by striking “2019” and insert-
18 ing “2025”;

19 (iii) in clause (i), by striking “2018”
20 and inserting “2024”; and

21 (iv) in subparagraph (B), by striking
22 “pandemic influenza” and inserting “a
23 pathogen causing a pandemic”; and

24 (D) in paragraph (6)—

1 (i) in subparagraph (A), in the matter
 2 preceding clause (i), by striking “The
 3 amounts described in this paragraph are
 4 the following amounts that are payable to
 5 an entity for activities described in this
 6 section of section 319C-2” and inserting
 7 “The Secretary shall withhold from an en-
 8 tity pursuant to paragraph (5) for non-
 9 compliance with the requirements of this
 10 section or section 319C-2 as follows”; and

11 (ii) in subparagraph (B), by inserting
 12 “with respect to the requirements of this
 13 section or section 319C-2” after “para-
 14 graph (5)”; and

15 (3) in subsection (h)—

16 (A) in paragraph (1)(A), by striking
 17 “\$685,000,000 for each of fiscal years 2019
 18 through 2023” and inserting “\$735,000,000
 19 for each of fiscal years 2024 through 2028”;

20 (B) in paragraph (4)—

21 (i) in subparagraph (A), by striking
 22 “For fiscal year 2027, the Secretary” and
 23 inserting “The Secretary”; and

24 (ii) in subparagraph (D), by striking
 25 “for fiscal year 2026”; and

1 (C) in paragraph (5)(A), by striking “For
2 fiscal year 2007, the Secretary” and inserting
3 “~~The Secretary~~”.

4 **SEC. 103. IMPROVING AND ENHANCING PARTICIPATION OF**
5 **EMS ORGANIZATIONS IN THE HOSPITAL PRE-**
6 **PAREDNESS PROGRAM.**

7 (a) INCREASING PARTICIPATION BY EMS IN THE
8 HOSPITAL PREPAREDNESS PROGRAM.—Section 319C-2
9 of the Public Health Service Act (42 U.S.C. 247d-3b) is
10 amended—

11 (1) in subsection (b)(1)(A)—

12 (A) in clause (iii)(III), by striking “; and”
13 and inserting semicolon; and

14 (B) by striking clause (iv) and inserting
15 the following:

16 “~~(iv) one or more emergency medical~~
17 ~~service organizations; and~~

18 “~~(v) to the extent practicable, one or~~
19 ~~more emergency management organiza-~~
20 ~~tions; and”;~~ and

21 (2) in subsection (g)(1)—

22 (A) by striking the heading and inserting:

23 “~~(1) LOCAL RESPONSE CAPABILITIES.—~~

24 “~~(A) PROGRAM COORDINATION.—~~”;

1 (B) by striking “extent practicable, en-
2 sure” and inserting the following: “extent prac-
3 ticable—

4 “(i) ensure”;

5 (C) by striking the period and inserting “;
6 and”; and

7 (D) by adding at the end the following:

8 “(ii) seek to increase participation of
9 eligible entities described in subsection
10 (b)(1)(A) with lower participation rates
11 relative to coalitions of other eligible enti-
12 ties, such as coalitions that include emer-
13 gency medical services organizations and
14 health care facilities in underserved
15 areas.”.

16 (b) PREFERENCES.—Section 319C-2(d)(1)(A)(iii) of
17 the Public Health Service Act (42 U.S.C. 247d-
18 3b(d)(1)(A)(iii)) is amended by striking “subsection
19 (b)(1)(A)(ii)” and inserting “clauses (ii) and (iv) of sub-
20 section (b)(1)(A)”.

21 **SEC. 104. IMPROVING MEDICAL READINESS AND RESPONSE**
22 **CAPABILITIES.**

23 Section 319C-2 of the Public Health Service Act (42
24 U.S.C. 247d-3b) is amended—

25 (1) in subsection (b)(2)—

1 (A) in subparagraph (A), by striking
2 “and” at the end;

3 (B) in subparagraph (B), by striking the
4 period and inserting “; and”; and

5 (C) by inserting at the end the following:

6 “(C) designate a lead entity to administer such
7 award and support coordination between entities de-
8 scribed in this subsection.”;

9 (2) in subsection (g)(1), as amended by section
10 102(a)(2), by adding at the end the following:

11 “(B) REGIONAL OPERATIONS.—An eligible
12 entity shall establish and maintain, or leverage
13 an existing, capability to enable coordination of
14 regional medical operations, which may include
15 systems to facilitate information sharing and
16 coordination, within a coalition described under
17 subsection (b)(1)(A) and, as appropriate, be-
18 tween multiple coalitions that are in close geo-
19 graphic proximity to each other.”; and

20 (3) in subsection (j)(1)—

21 (A) in subparagraph (A), by striking
22 “2019 through 2023” and inserting “2024
23 through 2028”; and

24 (B) in subparagraph (B)(iii), by striking
25 “2023” and inserting “2028”.

1 **SEC. 105. PILOT PROGRAM TO SUPPORT STATE MEDICAL**
2 **STOCKPILES.**

3 (a) **IN GENERAL.**—Section 319F-2(i) of the Public
4 Health Service Act (42 U.S.C. 247d-6b(i)) is amended—

5 (1) in paragraph (2)(B)(i)—

6 (A) in subclause (I), by striking “and
7 2024” and inserting “through 2025”; and

8 (B) in subclause (II), by striking “2025”
9 and inserting “2026”;

10 (2) in paragraph (4)—

11 (A) in subparagraph (G), by striking “;
12 and” at the end and inserting a semicolon;

13 (B) by redesignating subparagraph (H) as
14 subparagraph (I);

15 (C) by inserting after subparagraph (G)
16 the following:

17 “(H) facilitate the sharing of best practices
18 between States within a consortia of States in
19 receipt of funding related to establishing and
20 maintaining a stockpile of medical products;
21 and”; and

22 (D) in subparagraph (I), as so redesign-
23 ated, by striking “State efforts” and inserting
24 “State or regional efforts”;

25 (3) by redesignating paragraphs (5) through
26 (9) as paragraphs (6) through (10), respectively;

1 (4) by inserting after paragraph (4) the fol-
2 lowing:

3 “(5) COORDINATION.—An entity in receipt of
4 an award under paragraph (1), in carrying out the
5 activities under this subsection, shall coordinate with
6 appropriate health care entities, health officials, and
7 emergency management officials within the jurisdic-
8 tion of such State or States.”; and

9 (5) in paragraph (10), as so redesignated, by
10 striking “\$2,500,000,000 for each of fiscal years
11 2023 and 2024” and inserting “such sums as may
12 be necessary for each of fiscal years 2024 through
13 2028”.

14 (b) GAO REPORT.—Section 2409(b) of the PRE-
15 VENT Pandemics Act (Public Law 117–328) is amend-
16 ed—

17 (1) in paragraph (2), by striking “; and” and
18 inserting a semicolon;

19 (2) in paragraph (3), by striking the period and
20 inserting “; and”; and

21 (3) by adding at the end the following:

22 “(4) the impact of any regional stockpiling ap-
23 proaches carried out under such subsection (i)(1) of
24 section 319F–2 of the Public Health Service Act (42
25 U.S.C. 247d–6b).”.

1 **SEC. 106. ENHANCING DOMESTIC WASTEWATER SURVEIL-**
 2 **LANCE FOR PATHOGEN DETECTION.**

3 (a) **IN GENERAL.**—Subtitle C of title XXVIII of the
 4 Public Health Service Act (42 U.S.C. 300hh–31 et seq.)
 5 is amended by adding at the end the following:

6 **“SEC. 2827. WASTEWATER SURVEILLANCE FOR PATHOGEN**
 7 **DETECTION.**

8 “(a) **WASTEWATER SURVEILLANCE SYSTEM.**—The
 9 Secretary, acting through the Director of the Centers for
 10 Disease Control and Prevention and in coordination with
 11 other Federal departments and agencies, shall award
 12 grants, contracts, or cooperative agreements to eligible en-
 13 tities to establish, maintain, or improve activities related
 14 to the detection and monitoring of infectious diseases
 15 through wastewater for public health emergency prepared-
 16 ness and response purposes.

17 “(b) **ELIGIBLE ENTITIES.**—To be eligible to receive
 18 an award under this section, an entity shall—

19 “(1) be a State, Tribal, or local health depart-
 20 ment, or a partnership between such a health de-
 21 partment and other public and private entities; and

22 “(2) submit to the Secretary an application at
 23 such time, in such manner, and containing such in-
 24 formation as the Secretary may reasonably require,
 25 which shall include—

1 “(A) a description of activities proposed to
2 be carried out pursuant to an award under sub-
3 section (a);

4 “(B) factors such entity proposes to use to
5 select wastewater sampling sites;

6 “(C) a plan for responding, as appropriate,
7 to findings from such wastewater sampling,
8 consistent with applicable plans developed by
9 such entity pursuant to section 319C-1;

10 “(D) a plan to sustain such wastewater
11 surveillance activities described in such applica-
12 tion following the conclusion of the award pe-
13 riod; and

14 “(E) any additional information the Sec-
15 retary may require.

16 “(e) CONSIDERATION.—In making awards under sub-
17 section (a), the Secretary may give priority to eligible enti-
18 ties that have submitted an application that—

19 “(1) details plans to provide public access to
20 data generated through such wastewater surveillance
21 activities in a manner that enables comparison to
22 such data generated by other recipients of an award
23 under subsection (a); and

24 “(2) provides an assessment of community
25 needs related to ongoing infectious disease moni-

1 toring, including burden of infectious diseases that
2 can be detected in wastewater and availability of
3 other forms of infectious disease surveillance.

4 “(d) USE OF FUNDS.—An eligible entity shall, as ap-
5 propriate, use amounts awarded under this section to—

6 “(1) establish, or enhance existing, capacity and
7 capabilities to conduct wastewater sampling, testing,
8 and related analysis;

9 “(2) conduct wastewater surveillance, as appro-
10 priate, at individual facilities, institutions, and loca-
11 tions in rural areas, in which there is an increased
12 risk of infectious disease outbreaks, or areas in
13 which wastewater is not treated through the relevant
14 local utility of the jurisdiction; and

15 “(3) implement projects that use evidence-based
16 or promising practices to conduct wastewater sur-
17 veillance activities.

18 “(e) PARTNERSHIPS.—In carrying out activities
19 under this section, eligible entities shall identify opportuni-
20 ties to partner with other public or private entities to le-
21 verage relevant capabilities maintained by such entities,
22 as appropriate and consistent with this section.

23 “(f) TECHNICAL ASSISTANCE.—The Secretary, in
24 consultation with the heads of other applicable Federal
25 agencies and departments, as appropriate, shall provide

1 technical assistance to recipients of awards under this sec-
 2 tion to facilitate the planning, development, and imple-
 3 mentation of activities described in subsection (d).

4 “(g) AUTHORIZATION OF APPROPRIATIONS.—To
 5 carry out this section, there is authorized to be appro-
 6 priated such sums as may be necessary for each of fiscal
 7 years 2024 through 2028.”

8 (b) WASTEWATER SURVEILLANCE RESEARCH.—

9 (1) IN GENERAL.—The Secretary of Health and
 10 Human Services (in this subsection referred to as
 11 the “Secretary”) shall continue to conduct or sup-
 12 port research on the use of wastewater surveillance
 13 to detect and monitor emerging infectious diseases,
 14 which may include—

15 (A) research to improve the efficiency of
 16 wastewater sample collection and analysis and
 17 increase the sensitivity and specificity of waste-
 18 water testing methods; and

19 (B) implementation and development of
 20 evidence-based practices to facilitate the esti-
 21 mation of population-level data within a com-
 22 munity.

23 (2) NON-DUPLICATION OF EFFORT.—The Sec-
 24 retary shall ensure that activities carried out under
 25 this subsection do not unnecessarily duplicate efforts

1 of other agencies and offices within the Department
2 of Health and Human Services related to wastewater
3 surveillance.

4 **SEC. 107. REAUTHORIZATION OF MOSQUITO ABATEMENT**
5 **FOR SAFETY AND HEALTH PROGRAM.**

6 Section 317S of the Public Health Service Act (42
7 U.S.C. 247b-21) is amended—

8 (1) in subsection (a)(3)(A), by striking “sub-
9 section (b)(3)” and inserting “subsection (b)(4)”;

10 (2) in subsection (b)—

11 (A) by redesignating paragraphs (3)
12 through (6) as paragraphs (4) through (7), re-
13 spectively; and

14 (B) by inserting after paragraph (2) the
15 following:

16 “(3) CONSIDERATIONS.—The Secretary may
17 consider the use of innovative and novel technology
18 for mosquito prevention and control in making
19 grants under paragraph (1).”;

20 (3) by amending subsection (d) to read as fol-
21 lows:

22 “(d) USES OF FUNDS.—Amounts appropriated under
23 subsection (f) may be used by the Secretary to provide
24 training and technical assistance with respect to the plan-
25 ning, development, and operation of assessments and

1 plans under subsection (a) and control programs under
 2 subsection (b). The Secretary may provide such training
 3 and technical assistance directly or through awards of
 4 grants or contracts to public and private entities.”; and
 5 (4) in subsection (f)(1), by striking “2019
 6 through 2023” and inserting “2024 through 2028”.

7 **TITLE II—FEDERAL PLANNING** 8 **AND COORDINATION**

9 **SEC. 201. ALL-HAZARDS EMERGENCY PREPAREDNESS AND** 10 **RESPONSE.**

11 Section 2811 of the Public Health Service Act (42
 12 U.S.C. 300hh–10) is amended—

13 (1) in subsection (b)—

14 (A) in paragraph (3)—

15 (i) by striking “Oversee advanced”

16 and inserting the following:

17 “(A) IN GENERAL.—Oversee advanced”;

18 and

19 (ii) by adding at the end following:

20 “(B) DEVELOPMENT OF REQUIRE-
 21 MENTS.—Lead the development and approval,
 22 and, on a routine basis, the review and update,
 23 of requirements for such countermeasures and
 24 products, including related capabilities, to in-
 25 form the advanced research, development, pro-

1 eurement, and replenishment decisions of the
2 Department of Health and Human Services.”;

3 (B) in paragraph (4)—

4 (i) in subparagraph (F)—

5 (I) in the matter preceding clause
6 (i), by striking “and in consultation
7 with the Secretary of Homeland Secu-
8 rity,”; and

9 (II) in clause (i), by inserting
10 “enhance” after “capabilities and”;
11 and

12 (ii) in subparagraph (G)—

13 (I) in clause (i), by striking
14 “based on” and inserting “based on—
15 ”;

16 (II) in clause (ii), by striking “;
17 and” at the end and inserting a semi-
18 colon;

19 (III) in clause (iii), by striking
20 the period and inserting “; and”;

21 (IV) by adding at the end the fol-
22 lowing:

23 “(iv) that include, as appropriate, par-
24 ticipation by relevant industry, academia,

1 professional societies, and other stake-
2 holders.”;

3 (iii) in subparagraph (H)—

4 (I) by inserting “and the Direc-
5 tor of the Office of Pandemic Pre-
6 paredness and Response” after “Secu-
7 rity Affairs”; and

8 (II) by inserting “and medical
9 product and supply capacity planning
10 pursuant to subparagraph (J), includ-
11 ing discussion of any relevant identi-
12 fied supply chain vulnerabilities” be-
13 fore the period at the end;

14 (iv) in subparagraph (I), by inserting
15 “the Director of the Office of Pandemic
16 Preparedness and Response Policy,” after
17 “Security Affairs,”; and

18 (v) in subparagraph (J)(i), in the
19 matter preceding subclause (I), by insert-
20 ing “(including ancillary medical supplies
21 and components of medical products, such
22 as active pharmaceutical ingredients, key
23 starting materials, and medical device com-
24 ponents)” after “supply needs”; and

25 (C) in paragraph (7)—

1 (i) in the matter preceding subpara-
 2 graph (A), by inserting “and the require-
 3 ments developed pursuant to paragraph
 4 (3)(B)” after “subsection (d)”;

5 (ii) by redesignating subparagraphs
 6 (E) and (F) as subparagraphs (F) and
 7 (G), respectively; and

8 (iii) by inserting after subparagraph
 9 (D) the following:

10 “(E) include a professional judgment of
 11 anticipated budget needs for each future fiscal
 12 year accounted for in such plan to account for
 13 the full range of anticipated medical counter-
 14 measure needs and life-cycle costs to address
 15 such priorities and requirements;”;

16 (2) in subsection (d)—

17 (A) by amending paragraph (1) to read as
 18 follows:

19 “(1) IN GENERAL.—Not later than March 15,
 20 2020, and biennially thereafter, the Assistant Sec-
 21 retary for Preparedness and Response shall develop
 22 and submit to the Committee on Health, Education,
 23 Labor, and Pensions of the Senate and the Com-
 24 mittee on Energy and Commerce of the House of
 25 Representatives a coordinated strategy for medical

1 countermeasures to address chemical, biological, ra-
 2 diological, and nuclear threats, informed by the re-
 3 quirements developed pursuant to subsection
 4 (b)(3)(B). Not later than 180 days after the submis-
 5 sion of such strategy to such committees, the Assist-
 6 ant Secretary for Preparedness and Response shall
 7 submit an accompanying implementation plan to
 8 such committees. In developing such a strategy and
 9 plan, the Assistant Secretary for Preparedness and
 10 Response shall consult with the Public Health Emer-
 11 gency Medical Countermeasures Enterprise estab-
 12 lished under section 2811-1.”; and

13 (B) in paragraph (2), in the matter pre-
 14 ceeding subparagraph (A), by inserting “strategy
 15 and” before “plan”; and

16 (3) in subsection (f)—

17 (A) in paragraph (1), in the matter pre-
 18 ceeding subparagraph (A), by inserting “, includ-
 19 ing an emerging infectious disease,” after “any
 20 such agent”; and

21 (B) in paragraph (2)(A), by striking
 22 “\$250,000,000 for each of fiscal years 2019
 23 through 2023” and inserting “\$335,000,000
 24 for each of fiscal years 2024 through 2028”.

1 **SEC. 202. NATIONAL HEALTH SECURITY STRATEGY.**

2 Section 2802 of the Public Health Service Act is
3 amended—

4 (1) in subsection (a)(3)—

5 (A) by striking “In 2022, the” and insert-
6 ing “The”; and

7 (B) by inserting “, maintaining, and sus-
8 taining” after “establishing”; and

9 (2) in subsection (b)—

10 (A) in paragraph (2)—

11 (i) in subparagraph (A), by inserting
12 “that support interagency coordination and
13 availability of information, as appropriate”
14 before the period;

15 (ii) in subparagraph (B), by inserting
16 “rapid testing,” after “and supplies,”;

17 (B) in paragraph (3)—

18 (i) in subparagraph (C), by inserting
19 “and current capacity of facilities within
20 such systems, as applicable” before the pe-
21 riod;

22 (ii) in subparagraph (D), by inserting
23 “and other medical products and medical
24 supplies directly related to responding to
25 chemical, biological, radiological, or nuclear
26 threats, including emerging infectious dis-

1 cases, and incidents covered by the Na-
2 tional Response Framework, as applicable
3 and consistent with the activities carried
4 out under section 2811(b)(4)(J)” before
5 the period; and

6 (iii) by adding at the end the fol-
7 lowing:

8 “(H) Supporting the availability of blood
9 and blood products with respect to public health
10 emergencies.”;

11 (C) in paragraph (5), by inserting “appli-
12 cable federally-funded activities and” after “(in-
13 cluding”;

14 (D) in paragraph (8)—

15 (i) in subparagraph (A), by inserting
16 “public health and medical” before “activi-
17 ties”; and

18 (ii) in subparagraph (B), by striking
19 “familiarity with” and inserting “under-
20 standing of, and coordination between,”;

21 (E) by redesignating paragraphs (9) and
22 (10) as paragraphs (10) and (12), respectively;

23 (F) by inserting after paragraph (8) the
24 following:

1 “(9) OTHER SETTINGS.—Supporting Federal,
2 State, local, and Tribal coordination and planning
3 with respect to facilities in which there is an in-
4 creased risk of infectious disease outbreaks, includ-
5 ing such facilities that address the needs of at-risk
6 individuals, in the event of a public health emer-
7 gency declared under section 319.”;

8 (G) by inserting after subparagraph (10),
9 as so redesignated, the following:

10 “(11) OTHER HAZARDS.—Assessing current
11 and potential health security threats from natural
12 disasters or other extreme weather events with re-
13 spect to public health and medical preparedness and
14 response.”; and

15 (H) by striking “tribal” each place it ap-
16 pears and inserting “Tribal”.

17 **SEC. 203. IMPROVING DEVELOPMENT AND DISTRIBUTION**
18 **OF DIAGNOSTIC TESTS.**

19 Section 319B of the Public Health Service Act (42
20 U.S.C. 247d–2) is amended to read as follows:

21 **“SEC. 319B. IMPROVING DEVELOPMENT AND DISTRIBUTION**
22 **OF DIAGNOSTIC TESTS.**

23 “(a) FRAMEWORK.—The Secretary shall develop,
24 make publicly available not later than 1 year after the date
25 of enactment of the Pandemic and All-Hazards Prepared-

1 ness and Response Act, and update not less frequently
2 than every 3 years thereafter, a strategic framework for
3 the rapid development, validation, authorization, manufac-
4 ture, procurement, and distribution of diagnostic tests,
5 and for rapid scaling of testing capacity, in response to
6 chemical, biological, radiological, or nuclear threats, in-
7 cluding infectious diseases for which a public health emer-
8 gency is declared under section 319, or that has signifi-
9 cant potential to cause such a public health emergency.

10 Such strategic framework shall take into consideration—

11 “(1) domestic capacity, including any such ca-
12 pacity established through partnerships with public
13 and private entities pursuant to subsection (c), to
14 support the development, validation, authorization,
15 manufacture, procurement, and distribution of tests;

16 “(2) novel technologies and platforms that may
17 be used to improve testing capabilities, including
18 high-throughput laboratory diagnostics, and point-
19 of-care diagnostics, and any such technologies to im-
20 prove the accessibility of such tests, and facilitate
21 the development and manufacture of diagnostic
22 tests;

23 “(3) medical supply needs related to testing, in-
24 cluding diagnostic testing, equipment, supplies, and
25 component parts, and any potential vulnerabilities

1 related to the availability of such medical supplies
2 and related planning, consistent with section
3 ~~2811(b)(4)(J)~~;

4 “(4) strategies for the rapid and efficient dis-
5 tribution of tests locally, regionally, or nationwide
6 and scaling laboratory testing capacity; and

7 “(5) assessing such strategies through drills
8 and operational exercises carried out under section
9 ~~2811(b)(4)(G)~~, as appropriate.

10 “(b) COORDINATION.—To inform the development
11 and update of the framework under subsection (a), and
12 in carrying out activities to implement such framework,
13 the Secretary shall coordinate with industry, States, local
14 governmental entities, Indian Tribes and Tribal organiza-
15 tions, and other relevant public and private entities.

16 “(c) CAPACITY BUILDING.—The Secretary may con-
17 tract with public and private entities, as appropriate, to
18 increase domestic capacity in the rapid development, vali-
19 dation, authorization, manufacture, procurement, and dis-
20 tribution of diagnostic tests, as appropriate, to State,
21 local, and Tribal health departments and other appro-
22 priate entities for immediate public health response activi-
23 ties to address an infectious disease with respect to which
24 a public health emergency is declared under section 319,

1 or that has significant potential to cause such a public
2 health emergency.”.

3 **SEC. 204. PILOT PROGRAM FOR PUBLIC HEALTH DATA**
4 **AVAILABILITY.**

5 (a) SITUATIONAL AWARENESS SYSTEM.—Section
6 319D of the Public Health Service Act (42 U.S.C. 247d–
7 4) is amended—

8 (1) in subsection (c)—

9 (A) in paragraph (1), by inserting “, and
10 facilitate the leveraging of relevant public
11 health data across the Department of Health
12 and Human Services” after “extent prac-
13 ticable”; and

14 (B) in paragraph (2)—

15 (i) in subparagraph (A)—

16 (I) by striking “among agencies”
17 and inserting “among, and direct
18 communication between, agencies”;

19 (II) by inserting “the sharing of
20 information from applicable public
21 health data systems,” after “Tech-
22 nology),”; and

23 (III) by striking “; and” at the
24 end and inserting a semicolon;

1 (ii) in subparagraph (B), by striking
2 the period at the end and inserting “;
3 and”; and

4 (iii) by adding at the end the fol-
5 lowing:

6 “(C) facilitate communication, including
7 bidirectional communication or other means of
8 communication, to enable timely information
9 sharing with State, local, and Tribal public
10 health officials, between agencies and offices of
11 the Department of Health and Human Services,
12 and with health care providers, as applicable
13 and appropriate.”;

14 (2) in subsection (d)—

15 (A) in paragraph (1)—

16 (i) by striking “, the Secretary may”
17 and inserting “and support the near real-
18 time public availability of data, as appro-
19 priate, pursuant to section 319D-2, the
20 Secretary shall establish a pilot program
21 to”; and

22 (ii) by striking “, in collaboration with
23 appropriate” and inserting “. Such States
24 or consortia of States shall carry out such
25 activities in collaboration with appropriate

1 stakeholders, such as health information
2 exchanges, laboratory information sys-
3 tems,”;

4 (B) in paragraph (2)(A), by inserting
5 “pursuant to paragraph (3)” after “may re-
6 quire”;

7 (C) by striking paragraph (6);

8 (D) by redesignating paragraphs (3)
9 through (5) as paragraphs (4) through (6), re-
10 spectively;

11 (E) by inserting after paragraph (2) the
12 following:

13 “(3) DATA PLAN.—For purposes of this sub-
14 section, the Secretary shall develop a plan for data
15 elements to be reported to the Secretary pertaining
16 to potentially catastrophic infectious disease out-
17 breaks, in such form and manner and at such timing
18 and frequency as determined by the Secretary. When
19 developing the plan under this subsection, the Sec-
20 retary shall—

21 “(A) align with the standards and imple-
22 mentation specifications adopted by the Sec-
23 retary under section 3004, where applicable,
24 and update, as necessary and consistent with
25 applicable requirements of subsection (b)(3)

1 and section 2823, uniform standards for appli-
 2 cable entities to report data elements;

3 “(B) consider the use of technologies that
 4 enable fast bulk exchange of data; and

5 “(C) ensure the data elements reported
 6 under this subsection and made publicly avail-
 7 able pursuant to section 319D-2 are made
 8 available consistent with applicable Federal and
 9 State privacy law, at a minimum.”; and

10 (F) in paragraph (4), as so redesignated—

11 (i) in subparagraph (A), by striking
 12 “emergencies;” and inserting “emer-
 13 gencies, including such diseases rec-
 14 ommended by the National Public Health
 15 Data Board established under section
 16 319D-2; and”;

17 (ii) in subparagraph (B), by striking
 18 “; and” and inserting a period; and

19 (iii) by striking subparagraph (C);

20 and

21 (3) in subsection (h)—

22 (A) in paragraph (1), by striking “2022
 23 and 2023” and inserting “2024 through 2028”;

24 and

1 (B) in paragraph (2), by striking “2022
2 and 2023” and inserting “2024 through 2028”.

3 (b) DATA SELECTION AND ACCESS.—Title III of the
4 Public Health Service Act (42 U.S.C. 241 et seq.) is
5 amended by inserting after section 319D–1 the following:

6 **“SEC. 319D–2. PUBLIC HEALTH DATA PILOT PROGRAM.**

7 “(a) IN GENERAL.—The Secretary shall—

8 “(1) establish and maintain a near real-time,
9 open source, public-facing, and publicly available
10 website to provide deidentified, aggregated data on
11 potentially catastrophic disease outbreaks, in accord-
12 ance with subsection (b); and

13 “(2) collect the data elements pertaining to
14 such diseases recommended pursuant to subsection
15 (b)(1)(B), using existing processes or any new pro-
16 cesses established pursuant to section 319D(d).

17 “(b) NATIONAL PUBLIC HEALTH DATA BOARD.—

18 “(1) IN GENERAL.—The Secretary shall estab-
19 lish a National Public Health Data Board to advise,
20 and make recommendations to the Secretary with re-
21 spect to potentially catastrophic infectious diseases
22 appropriate for inclusion in the public health situa-
23 tional awareness system pilot program established
24 pursuant to section 319D(d) and the website estab-
25 lished under subsection (a)(1).

1 “(2) MEMBERSHIP.—The Board established
2 under paragraph (1) shall consist of the following
3 members:

4 “(A) FEDERAL MEMBERS.—The following
5 Federal members:

6 “(i) The Secretary of Health and
7 Human Services:

8 “(ii) The Secretary of Defense.

9 “(iii) The Secretary of Veterans Af-
10 fairs:

11 “(iv) The National Coordinator for
12 Health Information Technology.

13 “(v) The Director of the National In-
14 stitutes of Health:

15 “(vi) The Director of the Centers for
16 Disease Control and Prevention.

17 “(vii) The Assistant Secretary for
18 Preparedness and Response.

19 “(viii) The Director of the Indian
20 Health Service:

21 “(ix) The Administrator of the Cen-
22 ters for Medicare & Medicaid Services:

23 “(x) The Commissioner of Food and
24 Drugs:

1 “(xi) Such other heads of depart-
2 ments, agencies, and offices as the Sec-
3 retary determines appropriate.

4 “(B) NON-FEDERAL MEMBERS.—Such
5 other individuals appointed by the Secretary—

6 “(i) who have relevant public health,
7 medical, or scientific expertise, including—

8 “(I) individuals with expertise or
9 experience in—

10 “(aa) State, local, or Tribal
11 health data systems or practices;
12 or

13 “(bb) health data standards
14 and technology systems, which
15 may include hospital, pharmacy,
16 laboratory information systems
17 and health information ex-
18 changes; and

19 “(II) representatives of national
20 public health organizations; and

21 “(ii) individuals with such other spe-
22 cific expertise as the Secretary determines
23 appropriate.

24 “(e) RULE OF CONSTRUCTION.—Nothing in this sec-
25 tion shall be construed to alter existing obligations under

1 regulations promulgated under section 264(c) of the
 2 Health Insurance Portability and Accountability Act of
 3 1996, and this section shall be applied in a manner that
 4 is consistent with applicable Federal and State privacy
 5 law, at a minimum.

6 “(d) NONDUPLICATION OF EFFORTS.—The Sec-
 7 retary shall ensure that the activities carried out by the
 8 Board under this section do not duplicate the efforts of
 9 other Federal advisory committees that advise and make
 10 recommendations to the Secretary.

11 “(e) SUNSET.—This section shall cease to have force
 12 or effect on September 30, 2028.”.

13 **SEC. 205. COMBATING ANTIMICROBIAL RESISTANCE.**

14 Section 319E of the Public Health Service Act (42
 15 U.S.C. 247d–5) is amended—

16 (1) in subsection (a)—

17 (A) in paragraph (1), by inserting “and ac-
 18 tivities” after “Federal programs”;

19 (B) in paragraph (2)—

20 (i) by striking “public health constitu-
 21 encies, manufacturers, veterinary and med-
 22 ical professional societies and others” and
 23 inserting “the Advisory Council described
 24 in subsection (b) and relevant public and
 25 private entities”; and

1 (ii) by inserting “, pursuant to para-
2 graph (4),” after “comprehensive plan”;

3 (C) by amending paragraph (3) to read as
4 follow:

5 “(3) AGENDA.—The task force described in
6 paragraph (1) shall consider factors the Secretary
7 considers appropriate, including factors to—

8 “(A) slow the emergence of resistant bac-
9 teria and fungi and prevent the spread of re-
10 sistant infections;

11 “(B) strengthen activities to combat resist-
12 ance with respect to zoonotic diseases;

13 “(C) advance development and use of rapid
14 and innovative capabilities, including diagnostic
15 tests, for identification and characterization of
16 resistant bacteria and fungi;

17 “(D) accelerate basic and applied research
18 and development for new antibiotics,
19 antifungals, and other related therapeutics and
20 vaccines; and

21 “(E) support international collaboration
22 and capacities for antimicrobial-resistance pre-
23 vention, detection, and control.”;

24 (D) by redesignating paragraph (4) as
25 paragraph (5); and

1 (E) by inserting after paragraph (3) the
2 following:

3 “(4) ACTION PLAN.—Not later than October 1,
4 2025, and every 5 years thereafter, the task force
5 described in paragraph (1) shall develop and submit
6 to the Committee on Health, Education, Labor, and
7 Pensions and the Committee on Appropriations of
8 the Senate and the Committee on Energy and Com-
9 merce and the Committee on Appropriations of the
10 House of Representatives a plan regarding Federal
11 programs and activities to combat antimicrobial re-
12 sistance, including measurable outcomes, as appro-
13 priate, informed by the agenda described in para-
14 graph (3) and input provided by the Advisory Coun-
15 cil described in subsection (b) and other relevant
16 stakeholders provided pursuant to paragraph (2).”;

17 (2) by redesignating subsections (b) through (o)
18 as subsections (e) through (p), respectively;

19 (3) by inserting after subsection (a) the fol-
20 lowing:

21 “(b) ADVISORY COUNCIL.—

22 “(1) IN GENERAL.—The Secretary may con-
23 tinue the Presidential Advisory Council on Com-
24 bating Antibiotic-Resistant Bacteria, referred to in
25 this subsection as the ‘Advisory Council’.

1 “(2) DUTIES.—The Advisory Council shall ad-
2 vise and provide information and recommendations
3 to the Secretary, acting through the Task Force es-
4 tablished under subsection (a), regarding Federal
5 programs and activities intended to reduce or com-
6 bat antimicrobial-resistant bacteria or fungi that
7 may present a public health threat and improve ca-
8 pabilities to prevent, diagnose, mitigate, or treat
9 such resistance. Such advice, information, and rec-
10 ommendations may be related to improving Federal
11 efforts related to factors described in subsection
12 (a)(3) and other topics related to antimicrobial re-
13 sistance, as appropriate.

14 “(3) MEETINGS AND COORDINATION.—

15 “(A) MEETINGS.—The Advisory Council
16 shall meet not less than biannually and, to the
17 extent practicable, in coordination with meet-
18 ings of the task force established under sub-
19 section (a).

20 “(B) COORDINATION.—The Advisory
21 Council shall, to the greatest extent practicable,
22 coordinate activities carried out by the Council
23 with the task force established under subsection
24 (a).

1 “(4) FACA.—Chapter 10 of title 5, United
2 States Code, shall apply to the activities and duties
3 of the Advisory Council.”; and

4 (4) in subsection (n), as so redesignated, by
5 striking “(f) through (j)” and inserting “(g) through
6 (k)”.

7 **SEC. 206. STRATEGIC NATIONAL STOCKPILE AND MATE-**
8 **RIAL THREATS.**

9 Section ~~319F-2~~ of the Public Health Service Act (~~42~~
10 U.S.C. ~~247d-6b~~) is amended—

11 (1) in subsection (a)—

12 (A) in paragraph (2)(B)(i), by striking
13 subclause (IV) and inserting the following:

14 “(IV) the emergency health secu-
15 rity threat or threats such counter-
16 measure procurement is intended to
17 address, including—

18 “(aa) whether such procure-
19 ment is consistent with meeting
20 emergency health security needs
21 associated with such threat or
22 threats; and

23 “(bb) in the case of a coun-
24 termeasure that addresses a bio-
25 logical agent, whether such agent

1 has an increased likelihood to be-
2 come resistant to, more resistant
3 to, or evade, such counter-
4 measure relative to other avail-
5 able medical countermeasures;”;
6 and

7 ~~(B)~~ in paragraph ~~(3)~~—

8 (i) in subparagraph ~~(B)~~, by striking
9 “are followed, regularly reviewed, and up-
10 dated with respect to such stockpile” and
11 inserting “with respect to such stockpile
12 are followed, regularly reviewed, and up-
13 dated to reflect best practices”;

14 (ii) by redesignating subparagraphs
15 ~~(H)~~ through ~~(K)~~ as subparagraphs ~~(I)~~
16 through ~~(L)~~, respectively; and

17 (iii) by inserting after subparagraph
18 ~~(G)~~ the following:

19 “~~(H)~~ utilize tools to enable the timely and
20 accurate tracking, including the location and
21 geographic distribution and utilization, of the
22 contents of the stockpile throughout the deploy-
23 ment of such contents;”;

24 ~~(2)~~ in subsection ~~(c)(2)(C)~~—

25 ~~(A)~~ by striking “promptly”; and

1 (B) by inserting “, not later than 60 days
2 after such determination”;

3 (3) in subsection (f)(1), by striking
4 “\$610,000,000 for each of fiscal years 2019 through
5 2021, and \$750,000,000 for each of fiscal years
6 2022 and 2023” and inserting “\$965,000,000 for
7 each of fiscal years 2024 through 2028”; and

8 (4) in subsection (g)(1), by striking “2019
9 through 2028” and inserting “2024 through 2033”.

10 **SEC. 207. MEDICAL COUNTERMEASURES FOR VIRAL**
11 **THREATS WITH PANDEMIC POTENTIAL.**

12 Section 319L of the Public Health Service Act (42
13 U.S.C. 247d–7e) is amended—

14 (1) in subsection (e)(4)—

15 (A) in subparagraph (D), by amending
16 clause (iii) to read as follows:

17 “(iii) conduct research to promote
18 strategic initiatives, such as—

19 “(I) rapid diagnostics;

20 “(II) broad spectrum
21 antimicrobials;

22 “(III) medical countermeasures
23 for virus families that have significant
24 potential to cause a pandemic, includ-
25 ing such countermeasures that take

1 either pathogen-specific or broad spec-
2 trum approaches; and

3 “(IV) technologies to improve the
4 production and use of medical coun-
5 termeasures, which may include vae-
6 cine-manufacturing technologies, dose-
7 sparing technologies, efficacy-increas-
8 ing technologies, platform tech-
9 nologies, technologies to administer
10 countermeasures, and technologies to
11 improve storage and transportation of
12 countermeasures.”; and

13 (B) in subparagraph (F), by amending
14 clause (ii) to read as follows:

15 “(ii) threats that—

16 “(I)(aa) consistently exist or con-
17 tinually circulate and have a signifi-
18 cant potential to become a pandemic,
19 such as pandemic influenza; or

20 “(bb) include priority virus fami-
21 lies and other viral pathogens with a
22 significant potential to cause a pan-
23 demic; and

24 “(II) may include the advanced
25 research and development, manufac-

1 turing; and appropriate stockpiling of
 2 qualified pandemic or epidemic prod-
 3 ucts; and products, technologies, or
 4 processes to support the advanced re-
 5 search and development of such coun-
 6 termeasures (including multiuse plat-
 7 form technologies for diagnostics, vac-
 8 cines, and therapeutics; virus seeds;
 9 clinical trial lots; novel virus strains;
 10 and antigen and adjuvant material);”;

11 (2) in subsection (d)(2), by striking
 12 “\$611,700,000 for each of fiscal years 2019 through
 13 2023” and inserting “\$950,000,000 for each of fis-
 14 cal years 2024 through 2028”; and

15 (3) in subsection (e)(1), by amending subpara-
 16 graph (D) to read as follows:

17 “(D) SUNSET.—This paragraph shall cease
 18 to have force or effect after September 30,
 19 2028.”.

20 **SEC. 208. PUBLIC HEALTH EMERGENCY MEDICAL COUN-**
 21 **TERMEASURES ENTERPRISE.**

22 Section 2811–1(e) of the Public Health Service Act
 23 (42 U.S.C. 300hh–10a(e)) is amended—

24 (1) in paragraph (1)—

1 (A) by redesignating subparagraph (D) as
2 subparagraph (E); and

3 (B) by inserting after subparagraph (C)
4 the following:

5 “(D) Assist the Secretary in developing
6 strategies for appropriate and evidence-based
7 allocation and distribution of countermeasures
8 to jurisdictions, in a manner that supports the
9 availability and use of such countermeasures,
10 for public health and medical preparedness and
11 response needs.”;

12 (2) in paragraph (2), by striking “, as appro-
13 priate”; and

14 (3) by adding at the end the following:

15 “(3) INFORMATION SHARING.—The Secretary
16 shall, as appropriate and in a manner that does not
17 compromise national security, share information re-
18 lated to recommendations made and strategies devel-
19 oped under subparagraphs (A) and (C) of paragraph
20 (1) with relevant stakeholders, including industry
21 and State, local, and Tribal public health depart-
22 ments.”.

1 **SEC. 209. STRENGTHENING PUBLIC HEALTH COMMUNICA-**
2 **TION.**

3 (a) **PUBLIC HEALTH COMMUNICATIONS ADVISORY**
4 **COMMITTEE.**—The Secretary of Health and Human Serv-
5 ices (referred to in this section as the “Secretary”) shall
6 establish an advisory committee to be known as the Public
7 Health Communications Advisory Committee (referred to
8 in this subsection as the “Advisory Committee”).

9 (b) **DUTIES.**—The Advisory Committee shall make
10 recommendations to the Secretary and report on—

11 (1) critical aspects of communication and dis-
12 semination of scientific and evidence-based public
13 health information during public health emergencies;

14 (2) research from relevant external stakeholders
15 related to evidence-based or evidence-informed strat-
16 egies and best practices to effectively communicate
17 and disseminate such information; and

18 (3) strategies to improve communication and
19 dissemination of scientific and evidence-based public
20 health information to the public and to improve com-
21 munication between Federal, State, local, and Tribal
22 health officials.

23 (c) **COMPOSITION.**—The Advisory Committee shall be
24 composed of—

1 (1) appropriate Federal officials, appointed by
2 the Secretary, who shall serve as nonvoting mem-
3 bers; and

4 (2) individuals, appointed by the Secretary, rep-
5 resenting a variety of States and rural and urban
6 areas, and each of whom that has—

7 (A) expertise in public health, including in-
8 dividuals with experience in State, local, and
9 Tribal health departments, medicine, commu-
10 nications, related technology, psychology, men-
11 tal health and substance use disorders, national
12 security;

13 (B) experience in leading community out-
14 reach; or

15 (C) expertise in other areas, as the Sec-
16 retary determines appropriate.

17 (d) DISSEMINATION.—The Secretary shall review the
18 recommendations of the Advisory Committee and, not
19 later than 180 days after receipt of the report under sub-
20 section (b), shall submit to the Committee on Health,
21 Education, Labor, and Pensions of the Senate and the
22 Committee on Energy and Commerce of the House of
23 Representatives a report describing any actions planned
24 by the Secretary related to this section.

1 (e) **TERMINATION.**—The Advisory Committee shall
 2 terminate 2 years after the date of enactment of this Act.

3 **SEC. 210. FELLOWSHIP AND TRAINING PROGRAMS.**

4 Section 317G of the Public Health Service Act (42
 5 U.S.C. 247b–8) is amended—

6 (1) by striking “The Secretary,” and inserting
 7 the following:

8 “(a) **IN GENERAL.**—The Secretary,”; and

9 (2) by adding at the end the following:

10 “(b) **NONCOMPETITIVE CONVERSION.**—

11 “(1) **IN GENERAL.**—The Secretary may non-
 12 competitively convert an individual who has com-
 13 pleted an epidemiology, surveillance, or laboratory
 14 fellowship or training program under subsection (a)
 15 to a career-conditional appointment without regard
 16 to the provisions of subchapter I of chapter 33 of
 17 title 5, United States Code, provided that individual
 18 meets qualification requirements for the appoint-
 19 ment.”.

20 **SEC. 211. ASSESSMENT OF COVID-19 MITIGATION POLICIES.**

21 (a) **GAO STUDY.**—The Comptroller General of the
 22 United States shall conduct a study on the economic im-
 23 pact and health outcomes associated with the response to
 24 the COVID-19 pandemic in the United States. Such study
 25 shall include—

1 (1) a summary of strategies used by local gov-
2 ernmental entities, States, and the Federal Govern-
3 ment to contain and mitigate the spread of COVID-
4 19 during the public health emergency declared
5 under section 319 of the Public Health Service Act
6 (42 U.S.C. 247d) on January 31, 2020, including—

7 (A) limitations on large gatherings of peo-
8 ple;

9 (B) the closure of schools, businesses,
10 houses of worship, and other facilities;

11 (C) masking policies;

12 (D) testing policies; and

13 (E) vaccination policies;

14 (2) an analysis and review of the scientific evi-
15 dence related to the effectiveness of such strategies
16 in preventing or mitigating the spread of COVID-
17 19, including estimates of the burden of disease and
18 death that were avoided through such interventions;

19 (3) an analysis and review of the economic and
20 health impacts of such strategies, including impacts
21 related to mental and physical health and student
22 learning loss; and

23 (4) an accounting of Federal funding used to
24 implement such strategies.

1 (b) REPORT.—Not later than 18 months after the
 2 date of enactment of this Act, the Comptroller General
 3 of the United States shall submit a report on the study
 4 under subsection (a) to the Committee on Health, Edu-
 5 cation, Labor, and Pensions of the Senate and the Com-
 6 mittee on Energy and Commerce of the House of Rep-
 7 resentatives. Such report shall include recommendations
 8 based on the findings of the study conducted under sub-
 9 section (a) regarding the impact of such strategies during
 10 the COVID-19 public health emergency, including how to
 11 improve future responses.

12 **TITLE III—ADDRESSING THE**
 13 **NEEDS OF ALL INDIVIDUALS**

14 **SEC. 301. TRANSITION OF CERTAIN COUNTERMEASURES**
 15 **BETWEEN COMPENSATION PROGRAMS.**

16 (a) TREATMENT OF CERTAIN INELIGIBLE REQUESTS
 17 RELATED TO COVID-19 COUNTERMEASURES.—

18 (1) REQUESTS INITIALLY SUBMITTED UNDER
 19 EICP.—

20 (A) IN GENERAL.—In the case of a request
 21 for compensation submitted under section
 22 319F-4 of the Public Health Service Act (42
 23 U.S.C. 247d-6e) for an injury or death related
 24 to a COVID-19 vaccine that the Secretary de-
 25 termines to be ineligible pursuant to subpara-

1 graph (B) of such section ~~319F-4(b)(4)~~, as
2 added by subsection (b)(1), the Secretary shall,
3 not later than 30 days after such determina-
4 tion, notify the individual submitting the re-
5 quest of such determination.

6 (B) SUBMISSION OF PETITION.—An indi-
7 vidual who receives a notification described in
8 subparagraph (A) shall be eligible to submit a
9 petition to the United States Court of Federal
10 Claims under section 2111 of the Public Health
11 Service Act (42 U.S.C. 300aa-11) with respect
12 to the same vaccine administration claimed in
13 the request submitted under section ~~319F-4~~ of
14 such Act (~~42 U.S.C. 247d-6e~~), provided that
15 such petition is submitted not later than the
16 later of—

17 (i) 1 year after receiving such notifi-
18 cation under subparagraph (A); or

19 (ii) the last date on which the indi-
20 vidual otherwise would be eligible to sub-
21 mit a petition relating to such injury, as
22 specified in section 2116 of the Public
23 Health Service Act (42 U.S.C. 300aa-16).

24 (C) ELIGIBILITY.—To be eligible to submit
25 a petition in accordance with subparagraph (B),

1 the petitioner shall have submitted the request
2 for compensation under section ~~319F-4~~ of the
3 Public Health Service Act that was determined
4 to be ineligible not later than the deadline for
5 filing a petition under section 2116 of the Pub-
6 lic Health Service Act (~~42 U.S.C. 300aa-16~~)
7 that applies with respect to the administration
8 of such vaccine.

9 ~~(2) REQUESTS INITIALLY SUBMITTED UNDER~~
10 ~~VICP.—~~

11 (A) IN GENERAL.—If a special master de-
12 termines that—

13 (i) a petition submitted under section
14 2111 of the Public Health Service Act (~~42~~
15 ~~U.S.C. 300aa-11~~) related to a COVID-19
16 vaccine is ineligible for the National Vac-
17 cine Injury Compensation Program under
18 subtitle 2 of title ~~XXI~~ of the Public Health
19 Service Act (~~42 U.S.C. 300aa-10 et seq.~~)
20 because it relates to a vaccine administered
21 at a time when the vaccine was not in-
22 cluded in the Vaccine Injury Table under
23 section 2114 of such Act (~~42 U.S.C.~~
24 ~~300aa-14~~); and

1 (ii) the vaccine was administered
2 when it was a covered countermeasure sub-
3 ject to a declaration under section 319F-
4 3(b) of such Act (42 U.S.C. 247d-6d(b));
5 the special master shall, not later than 30 days
6 after such determination, notify the petitioner
7 of such determination.

8 (B) SUBMISSION OF REQUEST.—An indi-
9 vidual who receives a notification described in
10 subparagraph (A) shall be eligible to submit a
11 request for compensation under section 319F-
12 4(b) of the Public Health Service Act (42
13 U.S.C. 247d-6e) with respect to the same vac-
14 eine administration claimed in the petition sub-
15 mitted under section 2111 of such Act—

16 (i) not later than 1 year after receiv-
17 ing such notification; or

18 (ii) in the case that the notification is
19 issued after judicial review of the petition
20 under subsection (e) or (f) of section 2112
21 of such Act (42 U.S.C. 300aa-12), not
22 later than 1 year after the decision of the
23 United States Court of Federal Claim or
24 the mandate is issued by the United States

1 Court of Appeals for the Federal Circuit
 2 pursuant to such subsection (e) or (f).

3 (C) ELIGIBILITY.—To be eligible to submit
 4 a request for compensation in accordance with
 5 subparagraph (B), the individual submitting the
 6 request shall have submitted the petition under
 7 section 2111 of the Public Health Service Act
 8 (42 U.S.C. 300aa-11) that was determined to
 9 be ineligible not later than one year after the
 10 date of administration of the vaccine.

11 (b) CHANGES TO CERTAIN PROGRAMS.—

12 (1) CICP.—Section 319F-4 of the Public
 13 Health Service Act (42 U.S.C. 247d-6e) is amend-
 14 ed—

15 (A) in subsection (b)(4)—

16 (i) by striking “Except as provided”
 17 and inserting the following:

18 “(A) IN GENERAL.—Except as provided”;

19 and

20 (ii) by adding at the end the fol-
 21 lowing:

22 “(B) EXCLUSION OF INJURIES CAUSED BY
 23 VACCINES ON THE VACCINE INJURY TABLE.—
 24 Notwithstanding any other provision of this sec-
 25 tion, no individual may be eligible for com-

1 pensation under this section with respect to a
2 vaccine that, at the time it was administered,
3 was included in the Vaccine Injury Table under
4 section 2114.”; and

5 (B) in subsection (d)(3)—

6 (i) by striking “This section” and in-
7 serting the following:

8 “(A) IN GENERAL.—This section”; and

9 (ii) by adding at the end the fol-
10 lowing:

11 “(B) EXHAUSTION OF REMEDIES.—A cov-
12 ered individual shall not be considered to have
13 exhausted remedies as described in paragraph
14 (1), nor be eligible to seek remedy under section
15 319F-3(d), unless such individual has provided
16 to the Secretary all supporting documentation
17 necessary to facilitate the determinations re-
18 quired under subsection (b)(4).”.

19 (2) VICP.—Title XXI of the Public Health
20 Service Act (42 U.S.C. 300aa-1 et seq.) is amend-
21 ed—

22 (A) in section 2111(a)(2)(A) (42 U.S.C.
23 300aa-11(a)(2)(A)), in the matter preceding
24 clause (i), by inserting “containing the informa-

1 tion required under subsection (e)” after “un-
2 less a petition”;

3 (B) in section 2112(d) (42 U.S.C. 300aa-
4 12(d))—

5 (i) by adding at the end of paragraph
6 (1) the following: “Such designation shall
7 not occur until the petitioner has filed all
8 materials required under section 2111(e).”;
9 and

10 (ii) in paragraph (3)(A)(ii), by strik-
11 ing “the petition was filed” and inserting
12 “on which the chief special master makes
13 the designation pursuant to paragraph
14 (1)”;

15 (C) in section 2114(e) (42 U.S.C. 300aa-
16 14(e))—

17 (i) in paragraph (2), in the matter
18 preceding subparagraph (A), by striking
19 “2 years” and inserting “6 months”; and

20 (ii) by adding at the end the fol-
21 lowing:

22 “(4) LICENSURE REQUIREMENT.—Notwith-
23 standing paragraphs (2) and (3), the Secretary may
24 not revise the Vaccine Injury Table to include a vac-
25 eine for which the Centers for Disease Control and

1 Prevention has issued a recommendation for routine
 2 use in children or pregnant women until at least one
 3 application for such vaccine has been approved
 4 under section 351. Upon such revision of the Vac-
 5 cine Injury Table, all vaccines to prevent the same
 6 infectious disease, including vaccines authorized
 7 under emergency use pursuant to section 564 of the
 8 Federal Food, Drug, and Cosmetic Act, shall be con-
 9 sidered included in the Vaccine Injury Table.”; and

10 ~~(D)~~ in section 2116 (42 U.S.C. 300aa-16);

11 by adding at the end the following:

12 “(d) CLARIFICATION.—Notwithstanding subsections
 13 (a) and (b), an injury or death related to a vaccine admin-
 14 istered at a time when the vaccine was a covered counter-
 15 measure subject to a declaration under section 319F-3(b)
 16 shall not be eligible for compensation under the Pro-
 17 gram.”.

18 **SEC. 302. ACCELERATING INJURY COMPENSATION PRO-**
 19 **GRAM ADMINISTRATION AND ENSURING PRO-**
 20 **GRAM INTEGRITY.**

21 (a) IN GENERAL.—Section 2112(c) of the Public
 22 Health Service Act (42 U.S.C. 300aa12(c)) is amended—

23 (1) in paragraph (1), by striking “not more
 24 than 8 special masters” and inserting “not fewer
 25 than 10 special masters”; and

1 (2) in paragraph (4)—

2 (A) by striking “a term of 4 years” and in-
3 serting “an initial term of 4 years”;

4 (B) by striking the second and third sen-
5 tences; and

6 (C) by adding at the end the following:
7 “An individual appointed as special master may
8 be reappointed to serve one or more additional
9 terms of up to 8 years each, pursuant to para-
10 graph (1), and subject to termination under
11 paragraphs (2) and (3).”

12 (b) PETITIONS FOR COMPENSATION.—Section
13 2111(a)(2)(A)(i) of the Public Health Service Act (42
14 U.S.C. 300aa-11(a)(2)(A)(i)) is amended—

15 (1) in subclause (I), by striking “, and” and in-
16 serting a semicolon;

17 (2) in subclause (II)—

18 (A) by moving the margin 2 ems to the
19 right; and

20 (B) by striking “, or” and inserting “;
21 and”; and

22 (3) by adding at the end the following:

23 “(III) the judgment described in subclause
24 (I) does not result from a petitioner’s motion to
25 dismiss the case; or”.

1 (e) COMPENSATION.—Section 2115(e)(1) of the Pub-
 2 lie Health Service Act (42 U.S.C. 300aa-15(e)(1)) is
 3 amended by adding at the end the following: “When mak-
 4 ing a determination of good faith under this paragraph,
 5 the special master or court may consider whether the peti-
 6 tioner demonstrated an intention to obtain compensation
 7 on such petition and was not merely seeking to satisfy the
 8 exhaustion requirement under section 2121(b).”.

9 **SEC. 303. COMPENSATION FOR INJURIES RELATING TO THE**
 10 **PUBLIC HEALTH EMERGENCY CAUSED BY**
 11 **SARS-COV-2.**

12 (a) IN GENERAL.—With respect to claims filed under
 13 the Countermeasure Injury Compensation Program (re-
 14 ferred to in this section as “the Program”) under section
 15 319F-4 of the Public Health Service Act (42 U.S.C.
 16 247d-6e) alleging a covered injury caused by the adminis-
 17 tration or use of a covered countermeasure pursuant to
 18 a declaration under section 319F-3(b) of such Act (42
 19 U.S.C. 247d-6d(b)) relating to COVID-19, the following
 20 shall apply:

21 (1) Notwithstanding the filing deadline applica-
 22 ble under section 319F-4, the claim shall be filed
 23 within 3 years of the administration or use of the
 24 covered countermeasure, or one year after enactment
 25 of this section, whichever is later, and, if a claim

1 filed under the Program with respect to such admin-
 2 istration or use was filed before the date of enact-
 3 ment of this Act and denied on the basis of having
 4 not been filed within the time period required under
 5 subsection (b)(4) of such section 319F-4, such claim
 6 may be refiled pursuant to this paragraph.

7 (2) With respect to a claim relating to the ad-
 8 ministration of a COVID-19 vaccine, such a claim
 9 may be filed under the Program only if the adminis-
 10 tration of such vaccine occurred prior to the addition
 11 of the vaccine to the Vaccine Injury Table under sec-
 12 tion 2114 of the Public Health Service Act (42
 13 U.S.C. 300aa-14).

14 (3) Not later than 9 months after the date of
 15 enactment of this section, the Secretary of Health
 16 and Human Services shall promulgate a covered
 17 countermeasure injury table pursuant to subsection
 18 (b)(5) of section 319F-4 of the Public Health Serv-
 19 ice Act (42 U.S.C. 247d-6c(b)(5)).

20 (b) PROFESSIONAL JUDGMENT BUDGET.—

21 (1) IN GENERAL.—The Secretary of Health and
 22 Human Services—

23 (A) in consultation with the Attorney Gen-
 24 eral, shall submit a budget outlining the re-
 25 source needs for each agency for purposes of

1 carrying out the National Vaccine Injury Com-
2 pensation Program under subtitle 2 of title XXI
3 of such Act (42 U.S.C. 300aa-10 et seq.) for
4 fiscal years 2024 through 2028; and

5 (B) shall submit a budget outlining re-
6 source needs for purposes of carrying out the
7 Countermeasures Injury Compensation Pro-
8 gram under section 319F-4 of the Public
9 Health Service Act (42 U.S.C. 247d-6e) for fis-
10 cal years 2024 through 2028.

11 (2) INCLUSIONS.—The budgets described in
12 subparagraphs (A) and (B) of paragraph (1) shall
13 include estimates of both the resources necessary to
14 process current backlogs and each program’s ability
15 to reduce processing times with respect to such pro-
16 fessional judgments.

17 (c) NASEM REPORT.—The Secretary of Health and
18 Human Services shall seek to enter into a contract with
19 the National Academies of Sciences, Engineering, and
20 Medicine under which such National Academies shall re-
21 port, not later than 3 years after the date of enactment
22 of this Act, on the Countermeasure Injury Compensation
23 Program under section 319F-4 of the Public Health Serv-
24 ice Act (42 U.S.C. 247d-6e), including recommendations
25 to improve the administration of such program and wheth-

1 er Congress should adjust the compensation payments
2 available under such program.

3 **SEC. 304. REVIEW OF REGULATIONS.**

4 The Secretary of Health and Human Services shall
5 update regulations, as needed for purposes of carrying out
6 the amendments made by sections 301 and 302.

7 **SEC. 305. SUPPORTING INDIVIDUALS WITH DISABILITIES,
8 OLDER ADULTS, AND OTHER AT-RISK INDI-
9 VIDUALS DURING EMERGENCY RESPONSES.**

10 (a) TECHNICAL ASSISTANCE CENTERS ON AT-RISK
11 INDIVIDUALS AND DISASTERS.—

12 (1) IN GENERAL.—The Secretary of Health and
13 Human Services (referred to in this section as the
14 “Secretary”) may, through grants, contracts, or co-
15 operative agreements to eligible entities, establish
16 more than one research, training, and technical as-
17 sistance centers to provide appropriate information,
18 training, and technical assistance to States, local-
19 ities, Tribes, and other applicable entities related to
20 addressing the unique needs and considerations of
21 at-risk individuals, as defined in section 2802(b)(4)
22 of the Public Health Service Act (42 U.S.C. 300hh-
23 1(b)(4)), in the event of a public health emergency
24 declared by the Secretary pursuant to section 319 of
25 the Public Health Service Act (42 U.S.C. 247d).

1 (2) RESPONSIBILITIES OF THE CENTERS.—The
2 centers established under paragraph (1) shall con-
3 duct activities for the purpose of—

4 (A) developing, identifying, evaluating, and
5 disseminating evidence-based or evidence-in-
6 formed strategies to improve health and other
7 related outcomes for at-risk individuals related
8 to public health emergencies, including by ad-
9 dressing such unique needs and considerations
10 in carrying out public health and medical activi-
11 ties to prepare for, respond to, and recover
12 from, such public health emergencies; and

13 (B) assisting applicable entities in the im-
14 plementation of such evidence-based strategies,
15 including through sub-grants, contracts, or co-
16 operative agreements.

17 (3) PRIORITY.—In awarding grants for activi-
18 ties described in this subsection, the Secretary shall
19 give priority to eligible entities with demonstrated
20 expertise in, and ability to carry out, the activities
21 described in paragraph (2).

22 (4) CONSULTATION.—In carrying out activities
23 under paragraph (2), the centers established under
24 paragraph (1) shall take into consideration relevant
25 findings and recommendations of, and, as appro-

1 appropriate, consult with, the National Advisory Com-
2 mittee on Individuals with Disabilities and Disasters
3 established under section ~~2811C~~ of the Public
4 Health Service Act (~~42 U.S.C. 300hh-10d~~), the Na-
5 tional Advisory Committee on Children and Disas-
6 ters under section ~~2811A~~ of such Act (~~42 U.S.C.~~
7 ~~300hh-10b~~), and the National Advisory Committee
8 on Seniors and Disasters under section ~~2811B~~ of
9 such Act (~~42 U.S.C. 300hh-10e~~).

10 (5) ~~REPORTS.~~—Not later than 2 years after the
11 date of enactment of this Act and every 2 years
12 thereafter, the Secretary shall submit to the Com-
13 mittee on Health, Education, Labor, and Pensions
14 of the Senate and the Committee on Energy and
15 Commerce of the House of Representatives a report
16 describing the activities carried out under this sub-
17 section during the preceding 2 fiscal years.

18 (6) ~~SUNSET.~~—This subsection shall cease to
19 have force or effect on September 30, 2028.

20 (b) ~~CRISIS STANDARDS OF CARE.~~—Not later than 2
21 years after the date of enactment of this Act, the Sec-
22 retary, acting through the Director of the Office for Civil
23 Rights of the Department of Health and Human Services,
24 shall issue guidance to States and localities on the develop-
25 ment or modification of State and local crisis standards

1 of care for use during the response to a public health
 2 emergency declared by the governor of a State or by the
 3 Secretary under section 319 of the Public Health Service
 4 Act (42 U.S.C. 247d), or a major disaster or emergency
 5 declared by the President under section 401 or 501, re-
 6 spectively, of the Robert T. Stafford Disaster Relief and
 7 Emergency Assistance Act (42 U.S.C. 5170, 5191) to en-
 8 sure that such standards of care are consistent with the
 9 nondiscrimination requirements of section 504 of the Re-
 10 habilitation Act of 1973 (29 U.S.C. 794), title II of the
 11 Americans with Disabilities Act of 1990 (42 U.S.C. 12131
 12 et seq.), and the Age Discrimination Act of 1975 (42
 13 U.S.C. 6101 et seq.).

14 **SEC. 306. NATIONAL ADVISORY COMMITTEES.**

15 (a) NATIONAL ADVISORY COMMITTEE ON CHILDREN
 16 AND DISASTERS.—Section 2811A of the Public Health
 17 Service Act (42 U.S.C. 300hh–10b) is amended—

18 (1) in subsection (c)—

19 (A) by striking “may provide advice” and
 20 inserting the following: “may provide—
 21 “(1) advice”;

22 (B) by striking the period and inserting “;
 23 and”;

24 (C) by adding at the end the following:

1 “(2) recommendations to the Director of the
2 Office of Pandemic Preparedness and Response Pol-
3 icy and to Congress with respect to the public health
4 and emergency preparedness needs of children.”;
5 and

6 (2) in subsection (g); by striking “2023” and
7 inserting “2028”.

8 (b) NATIONAL ADVISORY COMMITTEE ON SENIORS
9 AND DISASTERS.—Section 2811B of the Public Health
10 Service Act (42 U.S.C. 300hh-10c) is amended—

11 (1) in subsection (c)—

12 (A) by striking “may provide advice” and
13 inserting the following: “may provide—
14 “(1) advice”;

15 (B) by striking the period and inserting “;
16 and”;

17 (C) by adding at the end the following:

18 “(2) recommendations to the Director of the
19 Office of Pandemic Preparedness and Response Pol-
20 icy and to Congress with respect to the public health
21 and emergency preparedness needs of seniors.”;

22 (2) in subsection (d)—

23 (A) in paragraph (1), by striking “17
24 members” and inserting “25 members”; and

25 (B) in paragraph (2)—

1 (i) in subparagraph (J), by striking
2 “2” and inserting “3”;

3 (ii) in subparagraph (K), by striking
4 “2” and inserting “3”;

5 (iii) by redesignating subparagraphs
6 (K) through (L) as subparagraphs (L)
7 through (M), respectively; and

8 (iv) by inserting after subparagraph
9 (J) the following:

10 “(K) At least 2 non-Federal health care
11 professionals with expertise in gerontology.”;
12 and

13 (3) by amending subsection (g) to read as fol-
14 lows:

15 “(g) SUNSET.—The Advisory Committee shall termi-
16 nate on September 30, 2028.”.

17 (e) NATIONAL ADVISORY COMMITTEE ON INDIVID-
18 UALS WITH DISABILITIES AND DISASTERS.—Section
19 2811C of the Public Health Service Act (42 U.S.C.
20 300hh–10d) is amended—

21 (1) by redesignating subsections (e) through (g)
22 as subsections (d) through (h), respectively;

23 (2) by inserting after subsection (b) the fol-
24 lowing:

1 “(e) ADDITIONAL DUTIES.—The Advisory Committee
2 may provide—

3 “(1) advice and recommendations to the Sec-
4 retary and to Congress with respect to individuals
5 with disabilities and the medical and public health
6 grants and cooperative agreements as applicable to
7 preparedness and response activities under this title
8 and title III; and

9 “(2) recommendations to the Director of the
10 Office of Pandemic Preparedness and Response Pol-
11 icy and to Congress with respect to the public health
12 and emergency preparedness needs of individuals
13 with disabilities.”;

14 (3) in subsection (d), as so redesignated—

15 (A) in paragraph (1), by striking “17
16 members” and inserting “25 members”;

17 (B) in paragraph (2)—

18 (i) by striking subparagraphs (K)
19 through (M); and

20 (ii) by inserting after subparagraph
21 (J) the following:

22 “(K) 15 non-Federal members (at least 4
23 of whom shall be individuals with disabilities)
24 from diverse backgrounds, including the fol-
25 lowing:

1 “(i) One representative from each of
2 the following:

3 “(I) A nongovernmental organi-
4 zation that provides disaster prepared-
5 ness and response services.

6 “(II) A community-based organi-
7 zation that represents individuals with
8 multiple types of disabilities.

9 “(III) A State-based organization
10 that represents individuals with mul-
11 tiple types of disabilities.

12 “(IV) A national organization
13 that represents individuals with mul-
14 tiple types of disabilities.

15 “(V) A national organization that
16 represents older adults.

17 “(VI) An organization that pro-
18 vides relevant housing services, includ-
19 ing during the response to, and recov-
20 ery from, disasters.

21 “(VII) An organization that rep-
22 resents disabled veterans.

23 “(ii) Four individuals with geographi-
24 cally diverse expertise in emergency man-
25 agement.

1 “~~(iii)~~ Two non-Federal health care
 2 professionals with expertise in disability ac-
 3 cessibility before, during, and after disas-
 4 ters, medical and mass care disaster plan-
 5 ning, preparedness, response, or recov-
 6 ery.”; and

7 (C) by adding at the end the following:

8 “~~(3)~~ CONSIDERATION.—In appointing members,
 9 including the Chair, to the Committee under this
 10 subsection, the Secretary may give consideration to
 11 disability status.”; and

12 (4) by amending subsection (h), as so redesign-
 13 nated, to read as follows:

14 “~~(h)~~ SUNSET.—The Advisory Committee shall termi-
 15 nate on September 30, 2028.”.

16 **SEC. 307. RESEARCH AND COORDINATION OF ACTIVITIES**
 17 **CONCERNING THE LONG-TERM HEALTH EF-**
 18 **FFECTS OF SARS-COV-2 INFECTION.**

19 (a) IN GENERAL.—The Secretary of Health and
 20 Human Services (referred to in this section as the “Sec-
 21 retary”) shall, as appropriate—

22 (1) coordinate activities among relevant Federal
 23 departments and agencies with respect to addressing
 24 the long-term health effects of SARS-CoV-2 infec-

1 tion, which may include conditions that arise as a
2 result of such infection;

3 ~~(2)~~ continue to conduct or support basic, clin-
4 ical, epidemiological, behavioral, and translational
5 research and public health surveillance related to the
6 pathogenesis, prevention, diagnosis, and treatment
7 of the long-term health effects of SARS-CoV-2 in-
8 fection and re-infection, which may include condi-
9 tions and any effects on development, cognition, and
10 neural structure and function that arise as a result
11 of such infection; and

12 ~~(3)~~ consistent with the findings of studies and
13 research under paragraph (1), in consultation with
14 health and public health professional associations,
15 scientific and medical researchers, and other rel-
16 evant experts, develop and inform recommendations,
17 guidance, and educational materials on the long-
18 term effects of SARS-CoV-2 infection, which may
19 include conditions that arise as a result of such in-
20 fection, and provide such recommendations, guid-
21 ance, and educational materials to health care pro-
22 viders and the general public.

23 (b) CONSIDERATIONS.—In conducting or supporting
24 research under this section, the Secretary shall consider
25 the diversity of research participants or cohorts to ensure

1 inclusion of a broad range of participants, as applicable
2 and appropriate.

3 (c) ~~ADDITIONAL ACTIVITIES.~~—The Secretary may—

4 (1) acting through the Director of the Agency
5 for Healthcare Research and Quality, conduct or
6 support research related to—

7 (A) the improvement of health care deliv-
8 ery for individuals experiencing long-term
9 health effects of SARS-CoV-2, which may in-
10 clude conditions that arise as a result of such
11 infection;

12 (B) the identification of any trends associ-
13 ated with differences in diagnosis and treat-
14 ment of the long-term health effects of SARS-
15 CoV-2 infection and related conditions; and

16 (C) the development or identification of
17 tools and strategies to help health care entities
18 and providers care for such populations, which
19 may include addressing any differences identi-
20 fied pursuant to subparagraph (B);

21 (2) publicly disseminate the results of such re-
22 search; and

23 (3) establish a primary care technical assistance
24 initiative to convene primary care providers and or-
25 ganizations, which may include support for con-

1 continuing training and education for such providers, as
2 applicable and appropriate, in order to collect and
3 disseminate best practices related to the care of indi-
4 viduals with long-term health effects of SARS-CoV-
5 2 infection, which may include conditions that arise
6 as a result of such infection.

7 (d) ANNUAL REPORTS.—Not later than 1 year after
8 the date of enactment of this Act, and annually thereafter
9 for the next 4 years, the Secretary shall prepare and sub-
10 mit a report to the Committee on Health, Education,
11 Labor, and Pensions of the Senate and the Committee on
12 Energy and Commerce of the House of Representatives
13 regarding an overview of the research conducted or sup-
14 ported under this section and any relevant findings. Such
15 reports may include information about how the research
16 and relevant findings under this section relate to other re-
17 search efforts supported by other public or private entities.

18 (e) PUBLIC AVAILABILITY OF INFORMATION.—In
19 making information or reports publicly available under
20 this section, the Secretary shall take into consideration the
21 delivery of such information in a manner that takes into
22 account the range of communication needs of the intended
23 recipients, including at-risk individuals.

1 **SEC. 308. NATIONAL ACADEMIES STUDY ON PRIZES.**

2 (a) **IN GENERAL.**—Not later than 90 days after the
3 date of enactment of this Act, the Secretary of Health and
4 Human Services shall seek to enter into an agreement
5 with the National Academies of Sciences, Engineering,
6 and Medicine (referred to in this section as the “National
7 Academies”) to conduct a study to examine—

8 (1) alternative models for directly funding, or
9 stimulating investment in, biomedical research and
10 development that delink research and development
11 costs from the prices of drugs, including the pro-
12 gressive replacement of patents and regulatory
13 exclusivities on new drugs with a combination of ex-
14 panded support for research and innovation prizes to
15 reward the successful development of drugs or
16 achievement of related milestones;

17 (2) the dollar amount of innovation prizes for
18 different stages of research and development of dif-
19 ferent classes or types of drugs, and total annual
20 funding, that would be necessary to stimulate invest-
21 ment sufficient to achieve such successful drug de-
22 velopment and related milestones;

23 (3) the relative effectiveness and efficiency of
24 such alternative models in stimulating innovation,
25 compared to the status quo that includes patents
26 and regulatory exclusivities;

1 (4) strategies to implement such alternative
2 models described in paragraph (1), including a
3 phased transition over time; and

4 (5) the anticipated economic and societal im-
5 pacts of such alternative models, including an as-
6 sessment of impact on—

7 (A) the number and variety of new drugs
8 that would be developed, approved, and mar-
9 keted in the United States, including such new
10 drugs intended to prevent, diagnose, or treat a
11 rare disease or condition;

12 (B) the rate at which new drugs would be
13 developed, approved, and marketed in the
14 United States;

15 (C) access to medication and health out-
16 comes;

17 (D) average lifespan and disease burden in
18 the United States;

19 (E) the number of manufacturers that
20 would be seeking approval for a drug or bring-
21 ing a drug to market for the first time;

22 (F) Federal discretionary and mandatory
23 spending; and

24 (G) public and private insurance markets.

1 (b) AUTHORIZATION OF APPROPRIATIONS.—To carry
2 out this section, there is authorized to be appropriated
3 \$3,000,000 for fiscal year 2024.

4 (c) REQUIREMENTS.—In conducting the study pursu-
5 ant to subsection (a), the National Academies shall hold
6 not fewer than 2 public listening sessions to solicit feed-
7 back from interested parties, including representatives of
8 academia, professional societies, patient advocates, public
9 health organizations, relevant Federal departments and
10 agencies, drug developers, representatives of other rel-
11 evant industries, and subject matter experts.

12 (d) REPORT.—Not later than 2 years after the date
13 of enactment of this Act, the National Academies shall
14 submit to the Committee on Health, Education, Labor,
15 and Pensions and the Committee on Appropriations of the
16 Senate and the Committee on Energy and Commerce and
17 the Committee on Appropriations of the House of Rep-
18 resentatives a report on the study conducted pursuant to
19 subsection (a).

1 **TITLE IV—STRENGTHENING**
2 **BIOSECURITY**

3 **SEC. 401. TREATMENT OF GENETIC VARIANTS AND SYN-**
4 **THETIC PRODUCTS OF SELECT AGENTS AND**
5 **TOXINS.**

6 Section 351A(a)(1) of the Public Health Service Act
7 (~~42 U.S.C. 262a(a)(1)~~) is amended by adding at the end
8 the following:

9 “(C) INCLUSIONS.—

10 “(i) IN GENERAL.—For purposes of
11 the list under this paragraph, the following
12 shall be considered to be a biological agent
13 or toxin included on the list:

14 “(I) Any biological agent that in-
15 corporates nucleic acids coding for a
16 virulence factor from a listed agent or
17 toxin.

18 “(II) Any biological agent or
19 toxin that is genetically homologous to
20 a listed agent or toxin with respect to
21 nucleotides coding for virulence fac-
22 tors or toxicity.

23 “(III) Any biological agent or
24 toxin that is synthetically derived with

1 virulence or toxicity characteristics of
2 a listed agent or toxin.

3 “(IV) Any nucleic acid that en-
4 codes for components contributing to
5 pathogenicity, transmissibility, or tox-
6 icity of a listed agent or toxin.

7 “(ii) EXEMPTIONS.—The Secretary
8 may exempt from inclusion on the list
9 under this paragraph any biological agent,
10 toxin, or nucleic acid described in clause
11 (i), if such agent, toxin, or nucleic acid
12 does not meet the criteria under subpara-
13 graph (B).”.

14 **SEC. 402. ESTABLISHMENT OF NO-FAULT REPORTING SYS-**
15 **TEM.**

16 Title III of the Public Health Service Act is amended
17 by inserting after section 351A (42 U.S.C. 262a) the fol-
18 lowing:

19 **“SEC. 351B. NO-FAULT REPORTING SYSTEM.**

20 “(a) DEFINITIONS.—In this section:

21 “(1) The term ‘listed agents and toxins’ has the
22 meaning given the term in section 351A(1).

23 “(2) The term ‘reporting system’ means the re-
24 porting system established under subsection (b)(1).

25 “(b) ESTABLISHMENT.—

1 “(1) IN GENERAL.—Not later than 3 years
2 after the date of enactment of the Pandemic and
3 All-Hazards Preparedness and Response Act, the
4 Secretary shall establish a confidential, anonymous,
5 voluntary, no-fault reporting system related to acci-
6 dents, near-accidents, or other safety incidents in-
7 volving biological agents and toxins, in order to sup-
8 port continuous improvement and sharing of lessons
9 learned related to such incidents.

10 “(2) AVAILABILITY.—The ability to submit re-
11 ports on a voluntary basis to the reporting system
12 shall be made available to individuals affiliated with
13 laboratories located in the United States, or at fed-
14 erally-funded entities outside the United States, that
15 conduct research involving biological agents and tox-
16 ins.

17 “(3) DATA.—Not later than 2 years after the
18 date of enactment of the Pandemic and All-Hazards
19 Preparedness and Response Act, the Secretary shall
20 publish a notice in the Federal Register on plans for
21 the reporting system, including—

22 “(A) data elements that will be included in
23 the submission of reports;

24 “(B) procedures and processes for the sub-
25 mission of reports;

1 “(C) criteria for incidents that may be re-
2 ported to such system; and

3 “(D) procedures for privacy and
4 anonymization.

5 “(4) PROTOTYPING AND TESTING.—The Sec-
6 retary shall test and prototype the reporting system
7 for not less than 1 year before finalizing the report-
8 ing system.

9 “(5) EXTERNAL FEEDBACK.—The Secretary
10 shall seek feedback on development of the reporting
11 system from external stakeholders, including prior to
12 publication of the information under paragraph (3)
13 and prior to introduction of prototypes and finaliza-
14 tion of such system under paragraph (4).

15 “(e) FOIA.—

16 “(1) IN GENERAL.—Information submitted to,
17 or derived from, the reporting system shall be ex-
18 empt from disclosure under section 552 of title 5,
19 United States Code.

20 “(2) APPLICABILITY.—For purposes of para-
21 graph (1), this section shall be considered a statute
22 described in section 552(b)(3)(B) of title 5, United
23 States Code.

24 “(d) PROHIBITION ON USE AS EVIDENCE.—Informa-
25 tion submitted to, or derived from, the reporting system

1 shall not be used in any Federal or State enforcement ac-
2 tion or criminal prosecution.

3 “(e) **PRIVACY; DISCIPLINARY ACTION FOR UNAU-**
4 **THORIZED DISCLOSURE.**—An individual or entity that
5 submits information to the reporting system under sub-
6 section (b) shall not be required to provide their name.

7 “(f) **RELATIONSHIP TO OTHER REPORTING SYS-**
8 **TEMS.**—The voluntary reporting system established under
9 this section shall supplement, and not supplant, any other
10 requirements to submit reports under any other reporting
11 system.”.

12 **SEC. 403. EVALUATION OF THE FEDERAL SELECT AGENT**
13 **PROGRAM AND RELATED POLICIES.**

14 (a) **IN GENERAL.**—Not later than 4 years after the
15 date of enactment of this Act, the National Science Advi-
16 sory Board for Biosecurity (referred to in this section as
17 the “Board”) established pursuant to section 4040 of the
18 Public Health Service Act (42 U.S.C. 283r) shall be
19 charged with assessing the framework for biosafety and
20 biosecurity oversight, particularly with respect to miti-
21 gating risks to the United States population with respect
22 to biological threats. The findings of the Board shall ad-
23 dress scientific advancements and integration of the Pro-
24 gram and other related Federal policies and frameworks

1 for biosafety and biosecurity. The findings of the Board
2 shall be transmitted to the President.

3 (b) FRAMEWORK.—

4 (1) IN GENERAL.—The recommendations devel-
5 oped under subsection (a) shall include a proposed
6 framework for an integrated approach to the over-
7 sight of biological research that raises significant
8 biosafety and biosecurity concerns, which may in-
9 clude proposals to harmonize and modernize relevant
10 Federal policies such as the following:

11 (A) The Federal Select Agent Program.

12 (B) Federal policies relating to dual-use
13 research of concern.

14 (C) Federal policies related to federally
15 funded research involving enhanced pathogens
16 of pandemic potential.

17 (D) The Biosafety in Microbiological and
18 Biomedical Laboratories Manual of the Depart-
19 ment of Health and Human Services, and other
20 related guidance documents.

21 (E) The Guidelines for Research Involving
22 Recombinant or Synthetic Nucleic Acid Mol-
23 ecules of the National Institutes of Health.

24 (2) REQUIREMENTS FOR FRAMEWORK.—The
25 framework proposed under paragraph (1) shall—

1 (A) be developed in consultation with
2 stakeholders and experts from institutions of
3 higher education, industry, and other govern-
4 ment agencies; and

5 (B) make recommendations related to miti-
6 gating any identified risks associated with exist-
7 ing gaps in oversight of such research, which
8 may include research that does not receive Fed-
9 eral funding; taking into consideration any na-
10 tional security concerns, the potential benefits
11 of such research, considerations related to the
12 research community, transparency, and public
13 availability of information, and international re-
14 search collaboration.

15 (c) REORGANIZATION.—In carrying out this section,
16 the Board may make recommendations related to the clar-
17 ification of the authorities and responsibilities of relevant
18 Federal departments and agencies and any necessary reor-
19 ganization of such authorities and responsibilities among
20 such departments and agencies.

21 (d) REPORT.—Not later than 1 year after the
22 issuance of recommendations under subsection (a), the
23 President shall submit to the Committee on Health, Edu-
24 cation, Labor, and Pensions of the Senate and the Com-
25 mittee on Energy and Commerce of the House of Rep-

1 representatives, and, as applicable, other appropriate commit-
 2 tees of Congress, a report that describes plans to consider
 3 and implement such recommendations, including the iden-
 4 tification of—

5 (1) any barriers to implementation; and

6 (2) any areas in which the President disagrees
 7 with the findings or recommendations of the Board.

8 **SEC. 404. SUPPORTING RESEARCH AND LABORATORY**
 9 **SURGE CAPACITY.**

10 (a) **IN GENERAL.**—The Secretary of Health and
 11 Human Services (referred to in this section as the “Sec-
 12 retary”) shall make awards to establish or maintain, as
 13 applicable, not fewer than 12 regional biocontainment lab-
 14 oratories, for purposes of—

15 (1) conducting biomedical research to support
 16 public health and medical preparedness for, and
 17 rapid response to, biological agents, including emerg-
 18 ing infectious diseases;

19 (2) ensuring the availability of surge capacity
 20 for purposes of responding to such biological agents;

21 (3) supporting information-sharing between,
 22 and the dissemination of findings to, researchers and
 23 other relevant individuals to facilitate collaboration
 24 between industry and academia; and

1 (4) providing, as appropriate and applicable,
2 technical assistance and training to researchers and
3 other relevant individuals to support the biomedical
4 research workforce in improving the management
5 and mitigation of safety and security risks in the
6 conduct of research involving such biological agents.

7 (b) REQUIREMENTS.—As a condition of receiving a
8 grant under this section, a regional biocontainment labora-
9 tory shall agree—

10 (1) to such oversight activities as the Secretary
11 determines appropriate, including periodic meetings
12 with relevant officials of the Department of Health
13 and Human Services, facility inspections, and other
14 activities as necessary and appropriate to ensure
15 compliance with the terms and conditions of such
16 award; and

17 (2) to report accidents, near-accidents, or other
18 safety incidents involving biological agents and tox-
19 ins into the no-fault reporting system established
20 pursuant to section 351B of the Public Health Serv-
21 ice Act, as added by section 402.

22 (c) BOARD.—The Secretary shall establish a Board
23 consisting of a representative from each entity in receipt
24 of an award under subsection (a), which shall be headed
25 by an executive committee of 3 members elected upon an

1 affirmative vote from a majority of such representatives.
2 The Board shall make recommendations to the Secretary
3 in administering awards under this section, for purposes
4 of—

5 (1) improving the quality and consistency of ap-
6 plicable procedures and practices within laboratories
7 funded pursuant to subsection (a); and

8 (2) ensuring coordination, as appropriate, of
9 federally funded activities carried out at such labora-
10 tories.

11 (d) DEFINITION.—In this section, the term “regional
12 biocontainment laboratory” means a Biosafety or Animal
13 Biosafety Level-3 and Level-2 facility located at an insti-
14 tution in the United States that is designated by the Sec-
15 retary to carry out the activities described in subsection
16 (a).

17 (e) AUTHORIZATION OF APPROPRIATIONS.—To carry
18 out this section, there are authorized to be appropriated
19 \$52,000,000 for each of fiscal years 2024 through 2028.

20 (f) ADMINISTRATIVE EXPENSES.—Of the amount
21 available to carry out this section for a fiscal year, the
22 Secretary may use not more than 5 percent for the admin-
23 istrative expenses of carrying out this section, including
24 expenses related to carrying out subsection (e).

1 (g) REPORT TO CONGRESS.—Not later than 1 year
2 after the date of the enactment of this Act, and biannually
3 thereafter, the Secretary, in consultation with the heads
4 of applicable Federal departments and agencies shall re-
5 port to the Committee on Health, Education, Labor, and
6 Pensions of the Senate and the Committee on Energy and
7 Commerce of the House of Representatives on—

8 (1) the activities and accomplishments of the
9 regional biocontainment laboratories;

10 (2) any published or disseminated research
11 findings based on research conducted in such labora-
12 tories in the applicable year;

13 (3) oversight activities carried out by the Sec-
14 retary pursuant to subsection (b);

15 (4) activities undertaken by the Secretary to
16 take into consideration the capacity and capabilities
17 of the network of regional biocontainment labora-
18 tories in activities to prepare for and respond to bio-
19 logical agents, which may include leveraging such ca-
20 pacity and capabilities to support the Laboratory
21 Response Network, as applicable and appropriate;

22 (5) plans for the maintenance and sustainment
23 of federally funded activities conducted at the re-
24 gional biocontainment laboratories, consistent with
25 the strategy required under section 2312 of the

1 PREVENT Pandemics Act (Public Law 117–328);
2 and

3 (6) activities undertaken by the Secretary to co-
4 ordinate with applicable agencies to ensure work car-
5 ried out by such facilities is prioritized and com-
6 plementary to one another, and avoiding unneces-
7 sary duplication.

8 **SEC. 405. GENE SYNTHESIS.**

9 (a) GUIDANCE.—Not later than 1 year after the date
10 of enactment of this Act, the Secretary of Health and
11 Human Services (referred to in this section as the “Sec-
12 retary”) shall update the Screening Framework Guidance
13 for Providers of Synthetic Double-Stranded DNA to ac-
14 count for scientific and technological advancements with
15 respect to mitigating risk of unauthorized individuals or
16 individuals with malicious intent from using nucleic acid
17 synthesis technologies to obtain biological agents or toxins
18 of concern. Such guidance shall include recommendations
19 related to—

20 (1) screening for sequences that the Secretary
21 determines may contribute to toxicity, pathogenicity,
22 or virulence;

23 (2) screening and verification of the identity
24 and legitimacy of customers;

1 (3) the identification, evaluation, and use of ap-
2 propriate software or other tools to enable the
3 screening described in paragraphs (1) and (2);

4 (4) ensuring nucleic acid synthesis activities are
5 carried out in compliance with existing regulations
6 under part 73 of title 42, Code of Federal Regula-
7 tions, part 331 of title 7, Code of Federal Regula-
8 tions, part 121 of title 9, Code of Federal Regula-
9 tions, and part 774 of title 15 Code of Federal Reg-
10 ulations (or successor regulations);

11 (5) implementing appropriate safeguards, which
12 may include the use of such software or other tools,
13 in gene synthesis equipment to facilitate screening of
14 nucleic acid sequences and, as applicable, customers;

15 (6) maintaining records of customer orders,
16 metadata, and screening system or protocol perform-
17 ance in specified formats, which may include stand-
18 ardized machine-readable and interoperable data for-
19 mats; and

20 (7) other recommendations as determined ap-
21 propriate by the Secretary.

22 (b) SEQUENCES OF CONCERN.—The Secretary shall
23 maintain a public docket to solicit recommendations on po-
24 tential sequences of concern and, in consultation with
25 other Federal departments and agencies and non-Federal

1 experts, as appropriate, review and update, on a regular
2 basis, a list of sequences of concern to facilitate screening
3 under subsection (a)(1).

4 (c) LANDSCAPE REVIEW.—The Secretary, in coordi-
5 nation with other Federal departments and agencies, as
6 appropriate, shall conduct a landscape review of providers
7 and manufacturers of gene synthesis equipment, products,
8 software, and other tools with the purpose of under-
9 standing the number, types, and capabilities of products
10 and equipment that exist domestically and to inform the
11 development of any updates to the guidance under sub-
12 section (a).

13 (d) TECHNICAL ASSISTANCE.—The Secretary, in
14 consultation with other Federal departments and agencies,
15 shall provide technical assistance upon request of a gene
16 synthesis provider, manufacturer of gene synthesis equip-
17 ment, or developer of software or other screening tools to
18 support implementation of the recommendations included
19 in the guidance under subsection (a).

20 (e) DEFINITIONS.—For purposes of this section:

21 (1) The term “gene synthesis equipment”
22 means equipment needed to produce gene synthesis
23 products.

24 (2) The term “gene synthesis product”—

1 (A) means custom single-stranded or dou-
2 ble-stranded DNA, or single-stranded or double-
3 stranded RNA, which has been chemically or
4 enzymatically synthesized or otherwise manu-
5 factured de novo and is of a length exceeding
6 the screening threshold, as determined by the
7 Secretary; and

8 (B) does not include—

9 (i) base chemical subunits, such as in-
10 dividual nucleotides or nucleosides, or
11 oligonucleotides shorter than the screening
12 threshold typically used as polymerase
13 chain reaction primers, as determined by
14 the Secretary;

15 (ii) by-products generated during se-
16 quencing that are not useful for assembly
17 or cloning, as determined by the Secretary;
18 or

19 (iii) products generated from cloning
20 or assembling of existing gene or gene
21 fragment material, in circumstances in
22 which the gene synthesis provider has no
23 access or notice to the sequence design, as
24 determined by the Secretary.

1 (3) The term “gene synthesis provider” means
2 an entity that synthesizes and distributes gene syn-
3 thesis products, including bacteria, viruses, or fungi
4 containing recombinant or synthetic nucleic acid
5 molecules, for delivery to a customer.

6 (4) The term “manufacturers of gene synthesis
7 equipment” means an entity that produces and sells
8 equipment for synthesizing gene synthesis products.

9 **SEC. 406. LIMITATION RELATED TO COUNTRIES OF CON-**
10 **CERN CONDUCTING CERTAIN RESEARCH.**

11 Section 2315(e) of the PREVENT Pandemics Act
12 (Public Law 117-328) is amended—

13 (1) in paragraph (1)—

14 (A) by inserting “that may reasonably be
15 anticipated to involve the creation, transfer, and
16 use of enhanced pathogens of pandemic poten-
17 tial or biological agents or toxins listed pursu-
18 ant to section 351A(a)(1) if such research is”
19 after “not fund research”; and

20 (B) by striking “, involving pathogens of
21 pandemic potential” and all that follows
22 through the period at the end and inserting a
23 period;

24 (2) in paragraph (2)—

1 (A) in the heading, by striking “CONDI-
2 TIONS FOR LISTING OR SUSPENDING PROHIBI-
3 TION” and inserting “LIMITATIONS”; and

4 (B) in the matter preceding subparagraph
5 (A)—

6 (i) by striking “The Secretary” and
7 inserting “Beginning 5 years after an ini-
8 tial determination of a country of concern,
9 the Director of National Intelligence or the
10 Secretary”; and

11 (ii) by inserting “with respect to such
12 country of concern” after “paragraph (1)”;
13 and

14 (3) by adding at the end the following:

15 “(3) CLARIFICATION.—

16 “(A) IN GENERAL.—The requirement of
17 paragraph (1) may be waived by the President
18 for the duration of the initial response to an
19 outbreak of a novel emerging infectious disease
20 if the President determines that such require-
21 ment impedes the ability of the Federal Govern-
22 ment to immediately respond to such outbreak.

23 “(B) NOTIFICATION.—The President shall
24 notify Congress not later than 48 hours after
25 exercising the waiver under subparagraph (A);

1 and shall provide updates to Congress related to
2 the use of such waiver every 15 days there-
3 after.”.

4 **SEC. 407. ASSESSMENT OF ARTIFICIAL INTELLIGENCE**
5 **THREATS TO HEALTH SECURITY.**

6 (a) **IN GENERAL.**—Not later than 45 days after the
7 date of enactment of this Act, the Secretary of Health and
8 Human Services (referred to in this section as the “Sec-
9 retary”) shall seek to enter into a contract with the Na-
10 tional Academies of Sciences, Engineering, and Medicine
11 (referred to in this section as the “National Academies”)
12 to conduct a study assessing the potential vulnerabilities
13 to health security presented by the current or prospective
14 use or misuse of artificial intelligence, including with re-
15 spect to open-source artificial intelligence models, such as
16 large language models.

17 (b) **INCLUSIONS.**—The study conducted pursuant to
18 the contract under subsection (a) shall include—

19 (1) an assessment of the potential
20 vulnerabilities posed by technical advancements in
21 artificial intelligence to health security, including
22 any risks related to the development of, enhance-
23 ment of, or protection from, chemical, biological, ra-
24 diological, or nuclear threats;

1 (2) a description of roles, responsibilities, and
2 capabilities of agencies and offices of the Depart-
3 ment of Health and Human Services, and, as appli-
4 cable and appropriate, other Federal departments
5 and agencies, with respect to the identification and
6 mitigation of such potential vulnerabilities;

7 (3) a summary of any ongoing Federal activi-
8 ties related to the identification, understanding, and
9 mitigation of such potential risks;

10 (4) the identification of any potential gaps,
11 whether current or anticipated, related to such roles,
12 responsibilities, and capabilities; and

13 (5) recommendations to improve Federal efforts
14 to identify, prepare for, and mitigate such potential
15 vulnerabilities.

16 (c) REPORTS.—

17 (1) NATIONAL ACADEMIES REPORT.—Not later
18 than 2 years after the date of the contract under
19 subsection (a), the National Academies shall submit
20 to the Committee on Health, Education, Labor, and
21 Pensions of the Senate and the Committee on En-
22 ergy and Commerce of the House of Representatives
23 a report on the study conducted pursuant to sub-
24 section (a).

(2) HHS REPORT.—Not later than 1 year after the issuance of the report required under paragraph (1), the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report detailing actions taken to mitigate and monitor risks to health security posed by misuse of artificial intelligence, as detailed in the report under paragraph (1).

TITLE V—PREVENTING DRUG SHORTAGES

SEC. 501. IMPROVING NOTIFICATION PROCEDURES IN CASE OF INCREASED DEMAND FOR CRITICAL DRUGS.

(a) IN GENERAL.—Section 506C of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356c) is amended—

(1) in the section heading, by striking “**DISCONTINUANCE OR INTERRUPTION IN THE PRODUCTION OF LIFE-SAVING DRUGS**” and inserting “**NOTIFICATION OF ISSUES AFFECTING DOMESTIC SUPPLY OF CRITICAL DRUGS**”;

(2) by striking subsections (a), (b), and (c), and inserting the following:

“(a) NOTIFICATION REQUIRED.—

1 “(1) IN GENERAL.—A manufacturer of a cov-
2 ered drug shall notify the Secretary, in accordance
3 with subsection (b), of—

4 “(A)(i) a permanent discontinuance in the
5 manufacture of the drug or an interruption of
6 the manufacture of the drug that is likely to
7 lead to a meaningful disruption in the supply of
8 such drug in the United States;

9 “(ii) a permanent discontinuance in the
10 manufacture of an active pharmaceutical ingre-
11 dient of such drug; or an interruption in the
12 manufacture of an active pharmaceutical ingre-
13 dient of such drug that is likely to lead to a
14 meaningful disruption in the supply of the ac-
15 tive pharmaceutical ingredient of such drug; or

16 “(iii) any other circumstance, such as an
17 increase in demand or export restriction, that is
18 likely to leave the manufacturer unable to meet
19 demand for the drug without a meaningful
20 shortfall or delay; and

21 “(B) the reasons for such discontinuance,
22 interruption, or other circumstance, if known.

23 “(2) CONTENTS.—Notification under this sub-
24 section with respect to a covered drug shall in-
25 clude—

1 “(A) with respect to the reasons for the
2 discontinuation, interruption, or other cir-
3 cumstance described in paragraph (1)(A)(iii), if
4 an active pharmaceutical ingredient is a reason
5 for, or risk factor in, such discontinuation,
6 interruption, or other circumstance, the source
7 of the active pharmaceutical ingredient and any
8 alternative sources for the active pharma-
9 ceutical ingredient known to the manufacturer;

10 “(B) whether any associated device used
11 for preparation or administration included in
12 the drug is a reason for, or a risk factor in,
13 such discontinuation, interruption, or other cir-
14 cumstance described in paragraph (1)(A)(iii);

15 “(C) the expected duration of the interrup-
16 tion; and

17 “(D) such other information as the Sec-
18 retary may require.

19 “(b) TIMING.—A notice required under subsection (a)
20 shall be submitted to the Secretary—

21 “(1) at least 6 months prior to the date of the
22 discontinuance or interruption;

23 “(2) in the case of such a notice with respect
24 to a circumstance described in subsection
25 (a)(1)(A)(iii), as soon as practicable, or not later

1 than 10 business days after the onset of the cir-
 2 cumstance; or

3 “(3) if compliance with paragraph (1) or (2) is
 4 not possible, as soon as practicable.

5 “(e) DISTRIBUTION.—To the maximum extent prac-
 6 ticable, the Secretary shall distribute, through such means
 7 as the Secretary determines appropriate, information on
 8 the discontinuance or interruption of the manufacture of,
 9 or other circumstance described in subsection
 10 (a)(1)(A)(iii) that is likely to lead to a shortage or mean-
 11 ingful disruption in the supply of, covered drugs to appro-
 12 priate organizations, including physician, health provider,
 13 and patient organizations, as described in section 506E.”;

14 (3) in subsection (g), in the matter preceding
 15 paragraph (1), by striking “drug described in sub-
 16 section (a)” and inserting “covered drug”; and

17 (4) in subsection (j), by striking “drug de-
 18 scribed in subsection (a)” and inserting “covered
 19 drug”.

20 (b) DEFINITIONS.—Paragraph (1) of section 506C(h)
 21 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
 22 356e(h)) is amended to read as follows:

23 “(1) the term ‘covered drug’ means a drug that
 24 is intended for human use and that—

25 “(A) is—

1 “(i) life-supporting;
 2 “(ii) life-sustaining; or
 3 “(iii) intended for use in the preven-
 4 tion or treatment of a debilitating disease
 5 or condition, including any such drug used
 6 in emergency medical care or during sur-
 7 gery or any such drug that is critical to
 8 the public health during a public health
 9 emergency declared by the Secretary under
 10 section 319 of the Public Health Service
 11 Act;

12 “(B) is not a radio pharmaceutical drug
 13 product or any other product as designated by
 14 the Secretary; and

15 “(C) is not a biological product (as defined
 16 in section 351(i) of the Public Health Service
 17 Act), unless otherwise provided by the Secretary
 18 in the regulations promulgated under subsection
 19 (i).”.

20 **SEC. 502. REPORTING ON SUPPLY CHAINS.**

21 Section 510(j)(3)(A) of the Federal Food, Drug, and
 22 Cosmetic Act (21 U.S.C. 360(j)(3)(A)) is amended—

23 (1) by inserting “, and the names and unique
 24 facility identifiers of the manufacturers of the active
 25 pharmaceutical ingredients such person used for the

1 manufacture, preparation, propagation,
2 compounding, or processing of such drug, and the
3 amount of such drug manufactured, prepared, prop-
4 agated, compounded, or processed using each such
5 active pharmaceutical ingredient from each such
6 manufacturer” before the period at the end of the
7 first sentence; and

8 (2) by inserting after the first sentence the fol-
9 lowing: “In addition to the reporting required under
10 the preceding sentence, the Secretary may receive
11 voluntary submissions of such information at more
12 frequent intervals.”.

13 **SEC. 503. REPORTING ON USE OF NEW AUTHORITIES AND**
14 **REQUIREMENTS WITH RESPECT TO DRUG**
15 **SHORTAGES.**

16 Not later than 90 days after the date of enactment
17 of this Act, the Secretary of Health and Human Services
18 (referred to in this section as the “Secretary”) shall report
19 to the Committee on Health, Education, Labor, and Pen-
20 sions of the Senate and the Committee on Energy and
21 Commerce of the House of Representatives on—

22 (1) the extent to which the Secretary has imple-
23 mented the authorities and requirements under sec-
24 tions 506C(g), 506C(j), 506E(d), 510(j)(3), and
25 704(b)(2) (21 U.S.C. 356e(g), 356e(j), 356e(d),

1 ~~360(j)(3), 374(b)(2)~~ of the Federal Food, Drug,
2 and Cosmetic Act, as amended by section ~~3111~~ and
3 ~~3112~~ of the Coronavirus Aid, Relief, and Economic
4 Security Act (Public Law ~~116-136~~), including—

5 (A) specific examples of uses of such au-
6 thorities and requirements; and

7 (B) an assessment of the extent to which
8 such authorities and requirements have helped
9 mitigate drug shortages; and

10 (2) the status of the guidance documents that
11 the Secretary intends to issue with respect to report-
12 ing and risk management plan requirements applica-
13 ble to manufacturers of drugs and active pharma-
14 ceutical ingredients, pursuant to the amendments
15 made to section ~~506C~~ of the Federal Food, Drug,
16 and Cosmetic Act (~~21 U.S.C. 356c~~) by subsections
17 (a) and (b) of section ~~3112~~ of the Coronavirus Aid,
18 Relief, and Economic Security Act (Public Law
19 ~~116-136~~).

1 **TITLE VI—ADDITIONAL REAU-**
2 **THORIZATIONS AND TECH-**
3 **NICAL AMENDMENTS**

4 **SEC. 601. MEDICAL COUNTERMEASURE PRIORITY REVIEW**
5 **VOUCHER.**

6 Section 565A(g) of the Federal Food, Drug, and Cos-
7 metic Act (21 U.S.C. 360bbb-4a) is amended by striking
8 “2023” and inserting “2028”.

9 **SEC. 602. EPIDEMIC INTELLIGENCE SERVICE LOAN REPAY-**
10 **MENT PROGRAM.**

11 Section 317F(e)(2) of the Public Health Service Act
12 (42 U.S.C. 247b-7(e)(2)) is amended by striking “2019
13 through 2023” and inserting “2024 through 2028”.

14 **SEC. 603. VACCINE TRACKING AND DISTRIBUTION.**

15 Section 319A(e) of the Public Health Service Act (42
16 U.S.C. 247d-1(e)) is amended by striking “2019 through
17 2023” and inserting “2024 through 2028”.

18 **SEC. 604. REGIONAL HEALTH CARE EMERGENCY PRE-**
19 **PAREDNESS AND RESPONSE SYSTEMS.**

20 Section 319C-3(e)(2) of the Public Health Service
21 Act (42 U.S.C. 247d-3e(e)(2)) is amended by striking
22 “2023” and inserting “2028”.

1 **SEC. 605. EMERGENCY SYSTEM FOR ADVANCE REGISTRA-**
 2 **TION OF VOLUNTEER HEALTH PROFES-**
 3 **SIONAL.**

4 Section 319I(k) of the Public Health Service Act (42
 5 U.S.C. 247d-7b(k)) is amended by striking “2019
 6 through 2023” and inserting “2024 through 2028”.

7 **SEC. 606. LIMITED ANTITRUST EXEMPTION.**

8 Section 319L-1(b) of the Public Health Service Act
 9 (42 U.S.C. 247d-7f(b)) is amended by striking “at the
 10 end of the 17-year period that begins on the date of enact-
 11 ment of this Act” and inserting “on September 30, 2028”.

12 **SEC. 607. TRAUMA CARE.**

13 Section 1232(a) of the Public Health Service Act (42
 14 U.S.C. 300d-32(a)) is amended by striking “\$24,000,000
 15 for each of fiscal years 2023 through 2027” and inserting
 16 “\$39,000,000 for each of fiscal years 2024 through
 17 2028”.

18 **SEC. 608. MILITARY AND CIVILIAN PARTNERSHIP FOR**
 19 **TRAUMA READINESS.**

20 Section 1291(g) of the Public Health Service Act (42
 21 U.S.C. 300d-91(g)) is amended by striking “2019
 22 through 2023” and inserting “2024 through 2028”.

23 **SEC. 609. NATIONAL DISASTER MEDICAL SYSTEM.**

24 (a) IN GENERAL.—Section 2812 of the Public Health
 25 Service Act (42 U.S.C. 300hh-11) is amended—

1 (1) in subsection (e)(4)(B), by striking “2023”
2 and inserting “2028”; and

3 (2) in subsection (g), by striking “\$57,400,000
4 for each of fiscal years 2019 through 2023” and in-
5 serting “\$65,900,000 for each of fiscal years 2024
6 through 2028”.

7 (b) REPEAL OF SUNSET.—

8 (1) IN GENERAL.—Section 301(d)(3) of the
9 Pandemic and All-Hazards Preparedness and Ad-
10 vancing Innovation Act of 2019 (Public Law 116-
11 22; 34 U.S.C. 10284 note) is repealed.

12 (2) EFFECTIVE DATE.— Paragraph (1) shall
13 take effect as if enacted on September 30, 2021.

14 **SEC. 610. VOLUNTEER MEDICAL RESERVE CORPS.**

15 Section 2813(i) of the Public Health Service Act (42
16 U.S.C. 300hh-15(i)) is amended by striking “2019
17 through 2023” and inserting “2024 through 2028”.

18 **SEC. 611. EPIDEMIOLOGY-LABORATORY CAPACITY GRANTS.**

19 Section 2821(b) of the Public Health Service Act (42
20 U.S.C. 300hh-31(b)) is amended, in the matter preceding
21 paragraph (1), by striking “2019 through 2023” and in-
22 serting “2024 through 2028”.

1 **SEC. 612. VETERANS AFFAIRS.**

2 Section 8117(g) of title 38, United States Code is
3 amended by striking “2019 through 2023” and inserting
4 “2024 through 2028”.

5 **SEC. 613. TECHNICAL AMENDMENTS.**

6 (a) Title XXI of the Public Health Service Act (42
7 U.S.C. 300aa-1 et seq.) is amended—

8 (1) in section 2105(b), by striking “, 2103, and
9 2104” each place it appears and inserting “and
10 2103”;

11 (2) in section 2110(b), by striking “the pro-
12 gram” and inserting “The Program”;

13 (3) in section 2111(a)—

14 (A) in paragraph (6), by striking “1988
15 for” and inserting “1988, for”; and

16 (B) in paragraph (10), by striking “United
17 States Claims Court” and inserting “United
18 States Court of Federal Claims”;

19 (4) in section 2112—

20 (A) in subsection (e)(6)(A), by striking
21 “United States Claims Courts” and inserting
22 “United States Court of Federal Claims”; and

23 (B) in subsection (f)—

24 (i) by striking “United States Claims
25 Court on” and inserting “United States
26 Court of Federal Claims on”; and

1 (ii) by striking “United States Claims
2 Court’s judgment” and inserting “judg-
3 ment of the United States Court of Fed-
4 eral Claims”;

5 (5) in section 2115(b)(3), by striking “sub-
6 section (e)” and inserting “subsection (e)”;

7 (6) in section 2117—

8 (A) in the section heading, by striking
9 “**SUBROGRATION**” and inserting “**SUBROGA-**
10 **TION**”; and

11 (B) in subsection (a), by striking
12 “subrograted” and inserting “subrogated”; and

13 (7) in section 2127—

14 (A) in subsection (b)(1), by inserting “and
15 Prevention” before the period; and

16 (B) in subsection (c), by striking “Com-
17 mittee on Labor and Human Resources” and
18 inserting “Committee on Health, Education,
19 Labor, and Pensions”.

20 (b) Section 319F-3 of the Public Health Service Act
21 (42 U.S.C. 247d-6d) is amended—

22 (1) in subsection (c)(5)(B)(ii)(I), by striking
23 “chapter 5” and inserting “chapter V”; and

24 (2) in subsection (i)(7)—

1 (A) by striking “~~321(g)(1)~~” and inserting
2 “~~321(g)(1)~~”; and

3 (B) by striking “~~321(h)~~” and inserting
4 “~~321(h)~~”.

5 (e) Section ~~319F-4~~ of the Public Health Service Act
6 (~~42 U.S.C. 247d-6e~~) is amended—

7 (1) in subsection (b)(1), by striking “under
8 ~~319F-3(b)~~” and inserting “under section ~~319F-~~
9 ~~3(b)~~”; and

10 (2) in subsection (d)(5), by striking “under
11 subsection (a) the Secretary determines that a cov-
12 ered individual qualifies for compensation” and in-
13 serting “a covered individual is determined under
14 subsection (a) to be eligible for compensation under
15 this section”.

16 (d) Part C of title II of the Public Health Service
17 Act (~~42 U.S.C. 239 et seq.~~) is amended—

18 (1) in section ~~261(a)(2)(A)~~, by striking “speci-
19 alities” and inserting “specialties”;

20 (2) in section ~~265(e)(5)~~, by striking “involves”
21 and inserting “involved”;

22 (3) in section ~~266(b)(3)(B)(ii)~~, by striking “to
23 with respect to an eligible” and inserting “with re-
24 spect to an eligible”; and

1 (4) in section 267(b), by striking “such Act”
2 and inserting “such part”.

3 (c) Section 351A(e)(7)(B)(ii) is amended by striking
4 “judical” and inserting “judicial”.

5 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

6 (a) *SHORT TITLE.*—*This Act may be cited as the*
7 *“Pandemic and All-Hazards Preparedness and Response*
8 *Act”.*

9 (b) *TABLE OF CONTENTS.*—*The table of contents for*
10 *this Act is as follows:*

Sec. 1. Short title; table of contents.

TITLE I—STATE AND LOCAL READINESS AND RESPONSE

Sec. 101. Temporary reassignment of State and local personnel during a public health emergency.

Sec. 102. Public Health Emergency Preparedness program.

Sec. 103. Improving and enhancing participation of EMS organizations in the hospital preparedness program.

Sec. 104. Improving medical readiness and response capabilities.

Sec. 105. Pilot program to support State medical stockpiles.

Sec. 106. Enhancing domestic wastewater surveillance for pathogen detection.

Sec. 107. Reauthorization of Mosquito Abatement for Safety and Health program.

TITLE II—FEDERAL PLANNING AND COORDINATION

Sec. 201. All-Hazards Emergency Preparedness and Response.

Sec. 202. National Health Security Strategy.

Sec. 203. Improving development and distribution of diagnostic tests.

Sec. 204. Pilot program for public health data availability.

Sec. 205. Combating antimicrobial resistance.

Sec. 206. Strategic National Stockpile and material threats.

Sec. 207. Medical countermeasures for viral threats with pandemic potential.

Sec. 208. Public Health Emergency Medical Countermeasures Enterprise.

Sec. 209. Strengthening public health communication.

Sec. 210. Fellowship and training programs.

Sec. 211. Assessment of COVID–19 mitigation policies.

Sec. 212. Emerging pathogens preparedness program.

TITLE III—ADDRESSING THE NEEDS OF ALL INDIVIDUALS

Sec. 301. Transition of certain countermeasures between compensation programs.

Sec. 302. Accelerating injury compensation program administration and ensuring program integrity.

- Sec. 303. Compensation for injuries relating to the public health emergency caused by SARS-CoV-2.*
- Sec. 304. Review of regulations.*
- Sec. 305. Supporting individuals with disabilities, older adults, and other at-risk individuals during emergency responses.*
- Sec. 306. National advisory committees.*
- Sec. 307. Research and coordination of activities concerning the long-term health effects of SARS-CoV-2 infection.*
- Sec. 308. National Academies study on prizes.*

TITLE IV—STRENGTHENING BIOSECURITY

- Sec. 401. Treatment of genetic variants and synthetic products of select agents and toxins.*
- Sec. 402. Establishment of no-fault reporting system.*
- Sec. 403. Evaluation of the Federal Select Agent Program and related policies.*
- Sec. 404. Supporting research and laboratory surge capacity.*
- Sec. 405. Gene synthesis.*
- Sec. 406. Limitation related to countries of concern conducting certain research.*
- Sec. 407. Assessment of artificial intelligence threats to health security.*

TITLE V—PREVENTING DRUG SHORTAGES

- Sec. 501. Improving notification procedures in case of increased demand for critical drugs.*
- Sec. 502. Reporting on supply chains.*
- Sec. 503. Reporting on use of new authorities and requirements with respect to drug shortages.*

TITLE VI—ADDITIONAL REAUTHORIZATIONS AND TECHNICAL AMENDMENTS

- Sec. 601. Medical countermeasure priority review voucher.*
- Sec. 602. Epidemic Intelligence Service loan repayment program.*
- Sec. 603. Vaccine tracking and distribution.*
- Sec. 604. Regional health care emergency preparedness and response systems.*
- Sec. 605. Emergency system for advance registration of volunteer health professional.*
- Sec. 606. Limited antitrust exemption.*
- Sec. 607. Trauma care.*
- Sec. 608. Military and civilian partnership for trauma readiness.*
- Sec. 609. National Disaster Medical System.*
- Sec. 610. Volunteer Medical Reserve Corps.*
- Sec. 611. Epidemiology-laboratory capacity grants.*
- Sec. 612. Veterans Affairs.*
- Sec. 613. Technical amendments.*

1 **TITLE I—STATE AND LOCAL**
 2 **READINESS AND RESPONSE**

3 **SEC. 101. TEMPORARY REASSIGNMENT OF STATE AND**
 4 **LOCAL PERSONNEL DURING A PUBLIC**
 5 **HEALTH EMERGENCY.**

6 *Section 319(e) of the Public Health Service Act (42*
 7 *U.S.C. 247d(e)) is amended—*

8 (1) *in paragraph (1), by striking “tribal organi-*
 9 *zation or such Governor or tribal organization’s des-*
 10 *ignee” and inserting “Tribal organization or the des-*
 11 *ignee of the Governor or Tribal organization, or the*
 12 *State or Tribal health official”;*

13 (2) *in paragraph (2)(B)—*

14 (A) *in the matter preceding clause (i), by*
 15 *striking “tribal organization” and inserting*
 16 *“Tribal organization, or the State or Tribal*
 17 *health official”; and*

18 (B) *in clause (v), by striking “tribal orga-*
 19 *nization” and inserting “Tribal organization or*
 20 *State or Tribal health official”;*

21 (3) *in paragraph (6)—*

22 (A) *in the matter preceding subparagraph*

23 (A)—

1 (i) by striking “Reauthorization Act of
2 2013” and inserting “and Response Act”;
3 and

4 (ii) by striking “appropriate commit-
5 tees of the Congress” and inserting “Com-
6 mittee on Health, Education, Labor, and
7 Pensions of the Senate and the Committee
8 on Energy and Commerce of the House of
9 Representatives”; and

10 (B) in subparagraph (A), by inserting “,
11 including requests from State or Tribal health
12 officials” before the semicolon;

13 (4) in paragraph (7)(A), by striking “tribal or-
14 ganization” and inserting “Tribal organization”; and

15 (5) in paragraph (8), by striking “2023” and in-
16 serting “2028”.

17 **SEC. 102. PUBLIC HEALTH EMERGENCY PREPAREDNESS**
18 **PROGRAM.**

19 Section 319C–1 of the Public Health Service Act (42
20 U.S.C. 247d–3a) is amended—

21 (1) in subsection (b)(2)—

22 (A) in subparagraph (A)(ii), by striking
23 “influenza” and inserting “response planning”;
24 and

1 (B) in subparagraph (H), by inserting “,
2 such as community-based organizations, includ-
3 ing faith-based organizations, and other public
4 and private entities” after “stakeholders”;

5 (2) in subsection (g)—

6 (A) in paragraph (1), in the matter pre-
7 ceding subparagraph (A), by inserting “and the
8 ability of each entity receiving an award under
9 subsection (a) to respond to all-hazards threats”
10 before the period at the end of the first sentence;

11 (B) in paragraph (2)—

12 (i) in the paragraph heading, by strik-
13 ing “INFLUENZA” and inserting “RE-
14 SPONSE”; and

15 (ii) in subparagraph (A)—

16 (I) by striking “to pandemic in-
17 fluenza” and inserting “to a pathogen
18 causing a pandemic, including pan-
19 demic influenza”; and

20 (II) by striking “such pandemic
21 influenza” and inserting “such pan-
22 demic response”;

23 (C) in paragraph (5)—

1 (i) in the paragraph heading, by strik-
2 ing “INFLUENZA” and inserting “PANDEMIC
3 RESPONSE”;

4 (ii) in the matter preceding subpara-
5 graph (A), by striking “2019” and inserting
6 “2025”;

7 (iii) in subparagraph (A), by striking
8 “2018” and inserting “2024”; and

9 (iv) in subparagraph (B), by striking
10 “pandemic influenza” and inserting “a
11 pathogen causing a pandemic”; and
12 (D) in paragraph (6)—

13 (i) in subparagraph (A), in the matter
14 preceding clause (i), by striking “The
15 amounts described in this paragraph are
16 the following amounts that are payable to
17 an entity for activities described in this sec-
18 tion of section 319C–2” and inserting “The
19 Secretary shall withhold from an entity
20 pursuant to paragraph (5) for noncompli-
21 ance with the requirements of this section or
22 section 319C–2 as follows”; and

23 (ii) in subparagraph (B), by inserting
24 “with respect to the requirements of this sec-

1 (A) in clause (iii)(III), by striking “; and”
2 and inserting a semicolon; and

3 (B) by striking clause (iv) and inserting the
4 following:

5 “(iv) one or more emergency medical
6 service organizations; and

7 “(v) to the extent practicable, one or
8 more emergency management organizations;
9 and”; and

10 (2) in subsection (g)(1)—

11 (A) by striking “(1) LOCAL RESPONSE CA-
12 PABILITIES” and inserting:

13 “(1) LOCAL RESPONSE CAPABILITIES.—

14 “(A) PROGRAM COORDINATION.—”;

15 (B) by striking “extent practicable, ensure”
16 and inserting the following: “extent prac-
17 ticable—

18 “(i) ensure”;

19 (C) by striking the period and inserting “;
20 and”; and

21 (D) by adding at the end the following:

22 “(ii) seek to increase participation of
23 eligible entities described in subsection
24 (b)(1)(A) with lower participation rates rel-
25 ative to other eligible entities, such as emer-

1 *gency medical services organizations and*
 2 *health care facilities in underserved areas.”.*

3 *(b) PREFERENCES.—Section 319C–2(d)(1)(A)(iii) of*
 4 *the Public Health Service Act (42 U.S.C. 247d–*
 5 *3b(d)(1)(A)(iii)) is amended by striking “subsection*
 6 *(b)(1)(A)(ii)” and inserting “clauses (ii) and (iv) of sub-*
 7 *section (b)(1)(A)”.*

8 **SEC. 104. IMPROVING MEDICAL READINESS AND RESPONSE**
 9 **CAPABILITIES.**

10 *Section 319C–2 of the Public Health Service Act (42*
 11 *U.S.C. 247d–3b) is amended—*

12 *(1) in subsection (b)(2)—*

13 *(A) in subparagraph (A), by striking “and”*
 14 *at the end;*

15 *(B) in subparagraph (B), by striking the*
 16 *period and inserting “; and”; and*

17 *(C) by inserting at the end the following:*

18 *“(C) designate a lead entity to administer such*
 19 *award and support coordination between entities de-*
 20 *scribed in this subsection.”;*

21 *(2) in subsection (g)(1), as amended by section*
 22 *103(a)(2), by adding at the end the following:*

23 *“(B) REGIONAL OPERATIONS.—An eligible*
 24 *entity shall establish and maintain, or leverage*
 25 *an existing, capability to enable coordination of*

1 regional medical operations, which may include
 2 systems to facilitate information sharing and co-
 3 ordination, within a coalition described under
 4 subsection (b)(1)(A) and, as appropriate, among
 5 multiple coalitions that are in close geographic
 6 proximity to each other.”; and

7 (3) in subsection (j)(1)—

8 (A) in subparagraph (A), by striking “2019
 9 through 2023” and inserting “2024 through
 10 2028”; and

11 (B) in subparagraph (B)(iii), by striking
 12 “2023” and inserting “2028”.

13 **SEC. 105. PILOT PROGRAM TO SUPPORT STATE MEDICAL**
 14 **STOCKPILES.**

15 (a) *IN GENERAL.*—Section 319F-2(i) of the Public
 16 Health Service Act (42 U.S.C. 247d-6b(i)) is amended—

17 (1) in paragraph (2)(B)(i)—

18 (A) in subclause (I), by striking “and
 19 2024” and inserting “through 2025”; and

20 (B) in subclause (II), by striking “2025”
 21 and inserting “2026”;

22 (2) in paragraph (4)—

23 (A) in subparagraph (G), by striking “;
 24 and” at the end and inserting a semicolon;

1 (B) by redesignating subparagraph (H) as
2 subparagraph (I);

3 (C) by inserting after subparagraph (G) the
4 following:

5 “(H) facilitate the sharing of best practices
6 among States within a consortia of States in re-
7 ceipt of funding related to establishing and
8 maintaining a stockpile of medical products;
9 and”;

10 (D) in subparagraph (I), as so redesignated,
11 by striking “State efforts” and inserting “State
12 or regional efforts”;

13 (3) by redesignating paragraphs (5) through (9)
14 as paragraphs (6) through (10), respectively;

15 (4) by inserting after paragraph (4) the fol-
16 lowing:

17 “(5) COORDINATION.—An entity in receipt of an
18 award under paragraph (1), in carrying out the ac-
19 tivities under this subsection, shall coordinate with
20 appropriate health care entities, health officials, and
21 emergency management officials within the jurisdic-
22 tion of such State or States.”;

23 (5) in paragraph (10), as so redesignated, by
24 striking “\$3,500,000,000 for each of fiscal years 2023

1 *and 2024” and inserting “such sums as may be nec-*
 2 *essary for each of fiscal years 2024 through 2028”.*

3 *(b) GAO REPORT.—Section 2409(b) of the PREVENT*
 4 *Pandemics Act (Public Law 117–328) is amended—*

5 *(1) in paragraph (2), by striking “; and” and*
 6 *inserting a semicolon;*

7 *(2) in paragraph (3), by striking the period and*
 8 *inserting “; and”; and*

9 *(3) by adding at the end the following:*

10 *“(4) the impact of any regional stockpiling ap-*
 11 *proaches carried out under subsection (i)(1) of section*
 12 *319F–2 of the Public Health Service Act (42 U.S.C.*
 13 *247d–6b).”.*

14 **SEC. 106. ENHANCING DOMESTIC WASTEWATER SURVEIL-**
 15 **LANCE FOR PATHOGEN DETECTION.**

16 *(a) IN GENERAL.—Subtitle C of title XXVIII of the*
 17 *Public Health Service Act (42 U.S.C. 300hh–31 et seq.) is*
 18 *amended by adding at the end the following:*

19 **“SEC. 2827. WASTEWATER SURVEILLANCE FOR PATHOGEN**
 20 **DETECTION.**

21 *“(a) WASTEWATER SURVEILLANCE SYSTEM.—The*
 22 *Secretary, acting through the Director of the Centers for*
 23 *Disease Control and Prevention and in coordination with*
 24 *other Federal departments and agencies, shall award*
 25 *grants, contracts, or cooperative agreements to eligible enti-*

1 *ties to establish, maintain, or improve activities related to*
2 *the detection and monitoring of infectious diseases through*
3 *wastewater for public health emergency preparedness and*
4 *response purposes.*

5 “(b) *ELIGIBLE ENTITIES.*—*To be eligible to receive an*
6 *award under this section, an entity shall—*

7 “(1) *be a State, Tribal, or local health depart-*
8 *ment, or a partnership between such a health depart-*
9 *ment and other public and private entities; and*

10 “(2) *submit to the Secretary an application at*
11 *such time, in such manner, and containing such in-*
12 *formation as the Secretary may reasonably require,*
13 *which shall include—*

14 “(A) *a description of activities proposed to*
15 *be carried out pursuant to an award under sub-*
16 *section (a);*

17 “(B) *factors such entity proposes to use to*
18 *select wastewater sampling sites;*

19 “(C) *a plan for responding, as appropriate,*
20 *to findings from such wastewater sampling, con-*
21 *sistent with applicable plans developed by such*
22 *entity pursuant to section 319C-1;*

23 “(D) *a plan to sustain such wastewater sur-*
24 *veillance activities described in such application*
25 *following the conclusion of the award period; and*

1 “(E) any additional information the Sec-
2 retary may require.

3 “(c) CONSIDERATION.—In making awards under sub-
4 section (a), the Secretary may give priority to eligible enti-
5 ties that have submitted an application that—

6 “(1) details plans to provide public access to
7 data generated through such wastewater surveillance
8 activities in a manner that enables comparison to
9 such data generated by other recipients of an award
10 under subsection (a); and

11 “(2) provides an assessment of community needs
12 related to ongoing infectious disease monitoring, in-
13 cluding burden of infectious diseases that can be de-
14 tected in wastewater and availability of other forms
15 of infectious disease surveillance.

16 “(d) USE OF FUNDS.—An eligible entity shall, as ap-
17 propriate, use amounts awarded under this section to—

18 “(1) establish or enhance existing capacity and
19 capabilities to conduct wastewater sampling, testing,
20 and related analysis;

21 “(2) conduct wastewater surveillance, as appro-
22 priate, at individual facilities, institutions, and loca-
23 tions in rural areas, in which there is an increased
24 risk of infectious disease outbreaks, or areas in which

1 wastewater is not treated through the relevant local
2 utility of the jurisdiction; and

3 “(3) implement projects that use evidence-based
4 or promising practices to conduct wastewater surveil-
5 lance activities.

6 “(e) *PARTNERSHIPS*.—In carrying out activities under
7 this section, eligible entities shall identify opportunities to
8 partner with other public or private entities to leverage rel-
9 evant capabilities maintained by such entities, as appro-
10 priate and consistent with this section.

11 “(f) *TECHNICAL ASSISTANCE*.—The Secretary, in con-
12 sultation with the heads of other applicable Federal agencies
13 and departments, as appropriate, shall provide technical
14 assistance to recipients of awards under this section to fa-
15 cilitate the planning, development, and implementation of
16 activities described in subsection (d).

17 “(g) *AUTHORIZATION OF APPROPRIATIONS*.—To carry
18 out this section, there is authorized to be appropriated such
19 sums as may be necessary for each of fiscal years 2024
20 through 2028.”.

21 (b) *WASTEWATER SURVEILLANCE RESEARCH*.—

22 (1) *IN GENERAL*.—The Secretary of Health and
23 Human Services (in this subsection referred to as the
24 “Secretary”) shall continue to conduct or support re-
25 search on the use of wastewater surveillance to detect

1 *and monitor emerging infectious diseases, which may*
 2 *include—*

3 *(A) research to improve the efficiency of*
 4 *wastewater sample collection and analysis and*
 5 *increase the sensitivity and specificity of waste-*
 6 *water testing methods; and*

7 *(B) implementation and development of evi-*
 8 *dence-based practices to facilitate the estimation*
 9 *of population-level data within a community.*

10 *(2) NON-DUPLICATION OF EFFORT.—The Sec-*
 11 *retary shall ensure that activities carried out under*
 12 *this subsection do not unnecessarily duplicate efforts*
 13 *of other agencies and offices within the Department of*
 14 *Health and Human Services related to wastewater*
 15 *surveillance.*

16 **SEC. 107. REAUTHORIZATION OF MOSQUITO ABATEMENT**
 17 **FOR SAFETY AND HEALTH PROGRAM.**

18 *Section 317S of the Public Health Service Act (42*
 19 *U.S.C. 247b–21) is amended—*

20 *(1) in subsection (a)(3)(A), by striking “sub-*
 21 *section (b)(3)” and inserting “subsection (b)(4)”;*

22 *(2) in subsection (b)—*

23 *(A) by redesignating paragraphs (3)*
 24 *through (6) as paragraphs (4) through (7), re-*
 25 *spectively; and*

1 (B) by inserting after paragraph (2) the fol-
2 lowing:

3 “(3) *CONSIDERATIONS.*—*The Secretary may con-*
4 *sider the use of innovative and novel technology for*
5 *mosquito prevention and control in making grants*
6 *under paragraph (1).”;*

7 (3) by amending subsection (d) to read as fol-
8 lows:

9 “(d) *USES OF FUNDS.*—*Amounts appropriated under*
10 *subsection (f) may be used by the Secretary to provide*
11 *training and technical assistance with respect to the plan-*
12 *ning, development, and operation of assessments and plans*
13 *under subsection (a) and control programs under subsection*
14 *(b). The Secretary may provide such training and technical*
15 *assistance directly or through awards of grants or contracts*
16 *to public and private entities.”; and*

17 (4) in subsection (f)(1), by striking “2019
18 through 2023” and inserting “2024 through 2028”.

19 **TITLE II—FEDERAL PLANNING**
20 **AND COORDINATION**

21 **SEC. 201. ALL-HAZARDS EMERGENCY PREPAREDNESS AND**
22 **RESPONSE.**

23 Section 2811 of the Public Health Service Act (42
24 U.S.C. 300hh–10) is amended—

25 (1) in subsection (b)—

1 (A) in paragraph (3)—

2 (i) by striking “Oversee advanced” and
3 inserting the following:

4 “(A) *IN GENERAL.*—Oversee advanced”; and

5 (ii) by adding at the end the following:

6 “(B) *DEVELOPMENT OF REQUIREMENTS.*—

7 *Lead the development and approval, and, on a*
8 *routine basis, the review and update, of require-*
9 *ments for such countermeasures and products,*
10 *including related capabilities, to inform the ad-*
11 *vanced research, development, procurement, and*
12 *replenishment decisions of the Secretary.”;*

13 (B) in paragraph (4)—

14 (i) in subparagraph (F)—

15 (I) in the matter preceding clause
16 (i), by striking “and in consultation
17 with the Secretary of Homeland Secu-
18 rity,”; and

19 (II) in clause (i), by inserting
20 “enhance” after “capabilities and”;

21 (ii) in subparagraph (G)—

22 (I) in clause (i), by striking
23 “based on” and inserting “based on—
24 ”;

1 (II) in clause (ii), by striking “;
2 and” at the end and inserting a semi-
3 colon;

4 (III) in clause (iii), by striking
5 the period and inserting “; and”; and

6 (IV) by adding at the end the fol-
7 lowing:

8 “(iv) that include, as appropriate, par-
9 ticipation by relevant industry, academia,
10 professional societies, and other stake-
11 holders.”;

12 (iii) in subparagraph (H)—

13 (I) by inserting “and the Director
14 of the Office of Pandemic Preparedness
15 and Response” after “Security Af-
16 fairs”; and

17 (II) by inserting “and medical
18 product and supply capacity planning
19 pursuant to subparagraph (J), includ-
20 ing discussion of any relevant identi-
21 fied supply chain vulnerabilities” be-
22 fore the period at the end;

23 (iv) in subparagraph (I), by inserting
24 “the Director of the Office of Pandemic Pre-

1 *paredness and Response Policy,*” after “*Se-*
2 *curity Affairs,*”; and

3 *(v) in subparagraph (J)(i), in the mat-*
4 *ter preceding subclause (I), by inserting*
5 *“(including ancillary medical supplies and*
6 *components of medical products, such as ac-*
7 *tive pharmaceutical ingredients, key start-*
8 *ing materials, and medical device compo-*
9 *ments)” after “supply needs”; and*

10 *(C) in paragraph (7)—*

11 *(i) in the matter preceding subpara-*
12 *graph (A), by inserting “and the require-*
13 *ments developed pursuant to paragraph*
14 *(3)(B)” after “subsection (d)”;*

15 *(ii) by redesignating subparagraphs*
16 *(E) and (F) as subparagraphs (F) and (G),*
17 *respectively; and*

18 *(iii) by inserting after subparagraph*
19 *(D) the following:*

20 *“(E) include a professional judgment of an-*
21 *ticipated budget needs for each future fiscal year*
22 *accounted for in such plan to account for the full*
23 *range of anticipated medical countermeasure*
24 *needs and life-cycle costs to address such prior-*
25 *ities and requirements;”;*

1 (2) *in subsection (d)—*

2 (A) *by amending paragraph (1) to read as*
3 *follows:*

4 “(1) *IN GENERAL.—Not later than March 15,*
5 *2020, and biennially thereafter, the Assistant Sec-*
6 *retary for Preparedness and Response shall develop*
7 *and submit to the Committee on Health, Education,*
8 *Labor, and Pensions of the Senate and the Committee*
9 *on Energy and Commerce of the House of Representa-*
10 *tives a coordinated strategy for medical counter-*
11 *measures to address chemical, biological, radiological,*
12 *and nuclear threats, informed by the requirements de-*
13 *veloped pursuant to subsection (b)(3)(B). Not later*
14 *than 180 days after the submission of such strategy*
15 *to such committees, the Assistant Secretary for Pre-*
16 *paredness and Response shall submit an accom-*
17 *panying implementation plan to such committees. In*
18 *developing such a strategy and plan, the Assistant*
19 *Secretary for Preparedness and Response shall consult*
20 *with the Public Health Emergency Medical Counter-*
21 *measures Enterprise established under section 2811–*
22 *1.”; and*

23 (B) *in paragraph (2), in the matter pre-*
24 *ceding subparagraph (A), by inserting “strategy*
25 *and” before “plan”; and*

1 (3) *in subsection (f)—*

2 (A) *in paragraph (1), in the matter pre-*
 3 *ceding subparagraph (A), by inserting “, includ-*
 4 *ing an emerging infectious disease,” after “any*
 5 *such agent”; and*

6 (B) *in paragraph (2)(A), by striking*
 7 *“\$250,000,000 for each of fiscal years 2019*
 8 *through 2023” and inserting “\$335,000,000 for*
 9 *each of fiscal years 2024 through 2028”.*

10 **SEC. 202. NATIONAL HEALTH SECURITY STRATEGY.**

11 Section 2802 of the Public Health Service Act is
 12 *amended—*

13 (1) *in subsection (a)(3)—*

14 (A) *by striking “In 2022, the” and insert-*
 15 *ing “The”; and*

16 (B) *by inserting “, maintaining, and sus-*
 17 *taining” after “establishing”; and*

18 (2) *in subsection (b)—*

19 (A) *in paragraph (2)—*

20 (i) *in subparagraph (A), by inserting*
 21 *“that support interagency coordination and*
 22 *availability of information, as appropriate”*
 23 *before the period;*

24 (ii) *in subparagraph (B), by inserting*
 25 *“rapid testing,” after “and supplies,”;*

1 (B) in paragraph (3)—

2 (i) in subparagraph (C), by inserting
3 “and current capacity of facilities within
4 such systems, as applicable” before the pe-
5 riod;

6 (ii) in subparagraph (D), by inserting
7 “and other medical products and medical
8 supplies directly related to responding to
9 chemical, biological, radiological, or nuclear
10 threats, including emerging infectious dis-
11 eases, and incidents covered by the National
12 Response Framework, as applicable and
13 consistent with the activities carried out
14 under section 2811(b)(4)(J)” before the pe-
15 riod; and

16 (iii) by adding at the end the fol-
17 lowing:

18 “(H) Supporting the availability of blood
19 and blood products with respect to public health
20 emergencies.”;

21 (C) in paragraph (5), by inserting “appli-
22 cable federally funded activities and” after “(in-
23 cluding”;

24 (D) in paragraph (8)—

1 (i) in subparagraph (A), by inserting
2 “public health and medical” before “activi-
3 ties”; and

4 (ii) in subparagraph (B), by striking
5 “familiarity with” and inserting “under-
6 standing of, and coordination between,”;

7 (E) by redesignating paragraphs (9) and
8 (10) as paragraphs (10) and (12), respectively;

9 (F) by inserting after paragraph (8) the fol-
10 lowing:

11 “(9) *OTHER SETTINGS.*—Supporting Federal,
12 State, local, and Tribal coordination and planning
13 with respect to facilities in which there is an in-
14 creased risk of infectious disease outbreaks, including
15 such facilities that address the needs of at-risk indi-
16 viduals, in the event of a public health emergency de-
17 clared under section 319.”;

18 (G) by inserting after subparagraph (10),
19 as so redesignated, the following:

20 “(11) *OTHER HAZARDS.*—Assessing current and
21 potential health security threats from natural disas-
22 ters or other extreme weather events with respect to
23 public health and medical preparedness and re-
24 sponse.”; and

1 (H) by striking “tribal” each place it ap-
2 pears and inserting “Tribal”.

3 **SEC. 203. IMPROVING DEVELOPMENT AND DISTRIBUTION**
4 **OF DIAGNOSTIC TESTS.**

5 Section 319B of the Public Health Service Act (42
6 U.S.C. 247d-2) is amended to read as follows:

7 **“SEC. 319B. IMPROVING DEVELOPMENT AND DISTRIBUTION**
8 **OF DIAGNOSTIC TESTS.**

9 “(a) *FRAMEWORK.*—The Secretary shall develop, make
10 publicly available not later than 1 year after the date of
11 enactment of the Pandemic and All-Hazards Preparedness
12 and Response Act, and update not less frequently than every
13 3 years thereafter, a strategic framework for the rapid devel-
14 opment, validation, authorization, manufacture, procure-
15 ment, and distribution of diagnostic tests, and for rapid
16 scaling of testing capacity, in response to chemical, biologi-
17 cal, radiological, or nuclear threats, including infectious
18 diseases for which a public health emergency is declared
19 under section 319, or that has significant potential to cause
20 such a public health emergency. Such strategic framework
21 shall take into consideration—

22 “(1) domestic capacity, including any such ca-
23 pacity established through partnerships with public
24 and private entities pursuant to subsection (c), to

1 *support the development, validation, authorization,*
2 *manufacture, procurement, and distribution of tests;*

3 *“(2) novel technologies and platforms that—*

4 *“(A) may be used to improve testing capa-*
5 *bilities, including—*

6 *“(i) high-throughput laboratory*
7 *diagnostics; and*

8 *“(ii) point-of-care diagnostics;*

9 *“(B) improve the accessibility of diagnostic*
10 *tests; and*

11 *“(C) facilitate the development and manu-*
12 *facture of diagnostic tests;*

13 *“(3) medical supply needs related to testing, in-*
14 *cluding diagnostic testing, equipment, supplies, and*
15 *component parts, and any potential vulnerabilities*
16 *related to the availability of such medical supplies*
17 *and related planning, consistent with section*
18 *2811(b)(4)(J);*

19 *“(4) strategies for the rapid and efficient dis-*
20 *tribution of tests locally, regionally, or nationwide*
21 *and scaling of laboratory testing capacity; and*

22 *“(5) assessment of such strategies through drills*
23 *and operational exercises carried out under section*
24 *2811(b)(4)(G), as appropriate.*

1 “(b) *COORDINATION.*—*To inform the development and*
 2 *update of the framework under subsection (a), and in car-*
 3 *rying out activities to implement such framework, the Sec-*
 4 *retary shall coordinate with industry, States, local govern-*
 5 *mental entities, Indian Tribes and Tribal organizations,*
 6 *and other relevant public and private entities.*

7 “(c) *CAPACITY BUILDING.*—*The Secretary may con-*
 8 *tract with public and private entities, as appropriate, to*
 9 *increase domestic capacity in the rapid development, vali-*
 10 *dation, authorization, manufacture, procurement, and dis-*
 11 *tribution of diagnostic tests, as appropriate, to State, local,*
 12 *and Tribal health departments and other appropriate enti-*
 13 *ties for immediate public health response activities to ad-*
 14 *dress an infectious disease with respect to which a public*
 15 *health emergency is declared under section 319, or that has*
 16 *significant potential to cause such a public health emer-*
 17 *gency.”.*

18 **SEC. 204. PILOT PROGRAM FOR PUBLIC HEALTH DATA**

19 **AVAILABILITY.**

20 (a) *SITUATIONAL AWARENESS SYSTEM.*—*Section*
 21 *319D of the Public Health Service Act (42 U.S.C. 247d–*
 22 *4) is amended—*

23 (1) *in subsection (c)—*

24 (A) *in paragraph (1), by inserting “, and*
 25 *shall facilitate the leveraging of relevant public*

1 *health data across the Department of Health and*
2 *Human Services” after “extent practicable”; and*

3 *(B) in paragraph (2)—*

4 *(i) in subparagraph (A)—*

5 *(I) by striking “among agencies”*
6 *and inserting “among, and direct com-*
7 *munication between, agencies”;*

8 *(II) by inserting “the sharing of*
9 *information from applicable public*
10 *health data systems,” after “Tech-*
11 *nology),”;* and

12 *(III) by striking “; and” at the*
13 *end and inserting a semicolon;*

14 *(ii) in subparagraph (B), by striking*
15 *the period at the end and inserting “; and”;*
16 *and*

17 *(iii) by adding at the end the fol-*
18 *lowing:*

19 *“(C) facilitate communication, including*
20 *bidirectional communication or other means of*
21 *communication, to enable timely information*
22 *sharing with State, local, and Tribal public*
23 *health officials, between agencies and offices of*
24 *the Department of Health and Human Services,*

1 *and with health care providers, as applicable*
2 *and appropriate.”;*

3 *(2) in subsection (d)—*

4 *(A) in paragraph (1)—*

5 *(i) by striking “, the Secretary may”*
6 *and inserting “and support the near real-*
7 *time public availability of data, as appro-*
8 *priate, pursuant to section 319D–2, the Sec-*
9 *retary shall establish a pilot program to”;*
10 *and*

11 *(ii) by striking “, in collaboration with*
12 *appropriate” and inserting “. Such States*
13 *or consortia of States shall carry out such*
14 *activities in collaboration with appropriate*
15 *stakeholders, such as health information ex-*
16 *changes, laboratory information systems,”;*

17 *(B) in paragraph (2)(A), by inserting “pur-*
18 *suant to paragraph (3)” after “may require”;*

19 *(C) by striking paragraph (6);*

20 *(D) by redesignating paragraphs (3)*
21 *through (5) as paragraphs (4) through (6), re-*
22 *spectively;*

23 *(E) by inserting after paragraph (2) the fol-*
24 *lowing:*

1 “(3) *DATA PLAN.*—*For purposes of this sub-*
2 *section, the Secretary shall develop a plan for data*
3 *elements to be reported to the Secretary pertaining to*
4 *potentially catastrophic infectious disease outbreaks,*
5 *in such form and manner and at such timing and*
6 *frequency as is determined by the Secretary. When de-*
7 *veloping the plan under this subsection, the Secretary*
8 *shall—*

9 “(A) *align with the standards and imple-*
10 *mentation specifications adopted by the Sec-*
11 *retary under section 3004, where applicable, and*
12 *update, as necessary and consistent with appli-*
13 *cable requirements of subsection (b)(3) and sec-*
14 *tion 2823, uniform standards for applicable enti-*
15 *ties to report data elements;*

16 “(B) *consider the use of technologies that*
17 *enable fast bulk exchange of data; and*

18 “(C) *ensure the data elements reported*
19 *under this subsection and made publicly avail-*
20 *able pursuant to section 319D–2 are made avail-*
21 *able consistent with applicable Federal and State*
22 *privacy law, at a minimum.”; and*

23 “(F) *in paragraph (4), as so redesignated—*

24 “(i) *in subparagraph (A), by striking*

25 *“emergencies;” and inserting “emergencies,*

1 including such diseases recommended by the
2 National Public Health Data Board estab-
3 lished under section 319D–2; and”;

4 (ii) in subparagraph (B), by striking
5 “; and” and inserting a period; and

6 (iii) by striking subparagraph (C);

7 and

8 (3) in subsection (h)—

9 (A) in paragraph (1), by striking “2022
10 and 2023” and inserting “2024 through 2028”;

11 and

12 (B) in paragraph (2), by striking “2022
13 and 2023” and inserting “2024 through 2028”.

14 (b) *DATA SELECTION AND ACCESS.*—Title III of the
15 Public Health Service Act (42 U.S.C. 241 et seq.) is amend-
16 ed by inserting after section 319D–1 the following:

17 **“SEC. 319D–2. PUBLIC HEALTH DATA PILOT PROGRAM.**

18 “(a) *IN GENERAL.*—The Secretary shall—

19 “(1) establish and maintain a near real-time,
20 open source, public-facing, and publicly available
21 website to provide deidentified, aggregated data on
22 potentially catastrophic disease outbreaks, in accord-
23 ance with subsection (b); and

24 “(2) collect the data elements pertaining to such
25 diseases recommended pursuant to subsection (b)(1),

1 *using existing processes or any new processes estab-*
2 *lished pursuant to section 319D(d).*

3 *“(b) NATIONAL PUBLIC HEALTH DATA BOARD.—*

4 *“(1) IN GENERAL.—The Secretary shall establish*
5 *a National Public Health Data Board to advise and*
6 *make recommendations to the Secretary with respect*
7 *to potentially catastrophic infectious diseases appro-*
8 *priate for inclusion in the public health situational*
9 *awareness system pilot program established pursuant*
10 *to section 319D(d) and the website established under*
11 *subsection (a)(1).*

12 *“(2) MEMBERSHIP.—The Board established*
13 *under paragraph (1) shall consist of the following*
14 *members:*

15 *“(A) FEDERAL MEMBERS.—The following*
16 *Federal members:*

17 *“(i) The Secretary of Health and*
18 *Human Services.*

19 *“(ii) The Secretary of Defense.*

20 *“(iii) The Secretary of Veterans Af-*
21 *fairs.*

22 *“(iv) The National Coordinator for*
23 *Health Information Technology.*

24 *“(v) The Director of the National In-*
25 *stitutes of Health.*

1 “(vi) *The Director of the Centers for*
2 *Disease Control and Prevention.*

3 “(vii) *The Assistant Secretary for Pre-*
4 *paredness and Response.*

5 “(viii) *The Director of the Indian*
6 *Health Service.*

7 “(ix) *The Administrator of the Centers*
8 *for Medicare & Medicaid Services.*

9 “(x) *The Commissioner of Food and*
10 *Drugs.*

11 “(xi) *Such other heads of departments,*
12 *agencies, and offices as the Secretary deter-*
13 *mines appropriate.*

14 “(B) *NON-FEDERAL MEMBERS.—Such other*
15 *individuals appointed by the Secretary—*

16 “(i) *who have relevant public health,*
17 *medical, or scientific expertise, including—*

18 “(I) *individuals with expertise or*
19 *experience in—*

20 “(aa) *State, local, or Tribal*
21 *health data systems or practices;*

22 *or*

23 “(bb) *health data standards*
24 *and technology systems, which*
25 *may include hospital, pharmacy,*

1 *and laboratory information sys-*
2 *tems, and health information ex-*
3 *changes;*

4 *“(II) representatives of national*
5 *public health organizations; and*

6 *“(ii) individuals with such other spe-*
7 *cific expertise as the Secretary determines*
8 *appropriate.*

9 *“(c) RULE OF CONSTRUCTION.—Nothing in this sec-*
10 *tion shall be construed to alter existing obligations under*
11 *regulations promulgated under section 264(c) of the Health*
12 *Insurance Portability and Accountability Act of 1996, and*
13 *this section shall be applied in a manner that is consistent*
14 *with applicable Federal and State privacy law, at a min-*
15 *imum.*

16 *“(d) NONDUPLICATION OF EFFORT.—The Secretary*
17 *shall ensure that the activities carried out by the Board*
18 *under this section do not duplicate the efforts of other Fed-*
19 *eral advisory committees that advise and make rec-*
20 *ommendations to the Secretary.*

21 *“(e) SUNSET.—This section shall cease to have force*
22 *or effect on September 30, 2028.”.*

23 **SEC. 205. COMBATING ANTIMICROBIAL RESISTANCE.**

24 *(a) IN GENERAL.—Section 319E of the Public Health*
25 *Service Act (42 U.S.C. 247d–5) is amended—*

1 (1) *in subsection (a)—*

2 (A) *in paragraph (1), by inserting “and ac-*
3 *tivities” after “Federal programs”;*

4 (B) *in paragraph (2)—*

5 (i) *by striking “public health constitu-*
6 *encies, manufacturers, veterinary and med-*
7 *ical professional societies and others” and*
8 *inserting “the Advisory Council described*
9 *in subsection (b) and relevant public and*
10 *private entities”; and*

11 (ii) *by inserting “, pursuant to para-*
12 *graph (4),” after “comprehensive plan”;*

13 (C) *by amending paragraph (3) to read as*
14 *follows:*

15 “(3) *AGENDA.—The task force described in para-*
16 *graph (1) shall consider factors the Secretary con-*
17 *siders appropriate, including factors to—*

18 “(A) *slow the emergence of resistant bac-*
19 *teria and fungi and prevent the spread of resist-*
20 *ant infections;*

21 “(B) *strengthen activities to combat resist-*
22 *ance with respect to zoonotic diseases;*

23 “(C) *advance development and use of rapid*
24 *and innovative capabilities, including diagnostic*

1 *tests, for identification and characterization of*
2 *resistant bacteria and fungi;*

3 “(D) *accelerate basic and applied research*
4 *and development for new antibiotics,*
5 *antifungals, and other related therapeutics and*
6 *vaccines; and*

7 “(E) *support international collaboration*
8 *and capacities for antimicrobial-resistance pre-*
9 *vention, detection, and control.”;*

10 (D) *by redesignating paragraph (4) as*
11 *paragraph (5);*

12 (E) *by inserting after paragraph (3) the fol-*
13 *lowing:*

14 “(4) *ACTION PLAN.—Not later than October 1,*
15 *2025, and every 5 years thereafter, the task force de-*
16 *scribed in paragraph (1) shall develop and submit to*
17 *the Committee on Health, Education, Labor, and*
18 *Pensions and the Committee on Appropriations of the*
19 *Senate and the Committee on Energy and Commerce*
20 *and the Committee on Appropriations of the House of*
21 *Representatives a plan regarding Federal programs*
22 *and activities to combat antimicrobial resistance, in-*
23 *cluding measurable outcomes, as appropriate, in-*
24 *formed by—*

25 “(A) *the agenda described in paragraph (3);*

1 “(B) input provided by the Advisory Coun-
2 cil described in subsection (b); and

3 “(C) input from other relevant stakeholders
4 provided pursuant to paragraph (2).”;

5 (2) by redesignating subsections (b) through (o)
6 as subsections (c) through (p), respectively;

7 (3) by inserting after subsection (a) the fol-
8 lowing:

9 “(b) *ADVISORY COUNCIL.*—

10 “(1) *IN GENERAL.*—The Secretary may continue
11 the Presidential Advisory Council on Combating An-
12 tibiotic-Resistant Bacteria, referred to in this sub-
13 section as the ‘Advisory Council’.

14 “(2) *DUTIES.*—The Advisory Council shall ad-
15 vise and provide information and recommendations
16 to the Secretary, acting through the Task Force estab-
17 lished under subsection (a), regarding Federal pro-
18 grams and activities intended to reduce or combat
19 antimicrobial-resistant bacteria or fungi that may
20 present a public health threat and improve capabili-
21 ties to prevent, diagnose, mitigate, or treat such re-
22 sistance. Such advice, information, and recommenda-
23 tions may be related to improving Federal efforts re-
24 lated to factors described in subsection (a)(3) and

1 *other topics related to antimicrobial resistance, as ap-*
2 *propriate.*

3 “(3) *MEETINGS AND COORDINATION.*—

4 “(A) *MEETINGS.*—*The Advisory Council*
5 *shall meet not less frequently than biannually*
6 *and, to the extent practicable, in coordination*
7 *with meetings of the task force established under*
8 *subsection (a).*

9 “(B) *COORDINATION.*—*The Advisory Coun-*
10 *cil shall, to the greatest extent practicable, co-*
11 *ordinate activities carried out by the Council*
12 *with the task force established under subsection*
13 *(a).*

14 “(4) *FACA.*—*Chapter 10 of title 5, United*
15 *States Code, shall apply to the activities and duties*
16 *of the Advisory Council.”; and*

17 *(4) in subsection (n), as so redesignated, by*
18 *striking “(f) through (j)” and inserting “(g) through*
19 *(k)”.*

20 (b) *CONFORMING AMENDMENT.*—*Section 505 of the*
21 *Pandemic and All-Hazards Preparedness and Advancing*
22 *Innovation Act of 2019 (42 U.S.C. 247d–5 note; Public Law*
23 *116–22) is amended by striking subsection (a) and all that*
24 *follows through “Not later” in subsection (e) and inserting*
25 *the following:*

1 *“Not later”.*

2 **SEC. 206. STRATEGIC NATIONAL STOCKPILE AND MATERIAL**
3 **THREATS.**

4 *Section 319F–2 of the Public Health Service Act (42*
5 *U.S.C. 247d–6b) is amended—*

6 *(1) in subsection (a)—*

7 *(A) in paragraph (2)(B)(i)—*

8 *(i) in subclause (II), in the matter pre-*
9 *ceding item (aa), by inserting “including*
10 *prioritizing such goals and identifying*
11 *metrics to measure success in meeting such*
12 *goals,” after “information),”; and*

13 *(ii) by striking subclause (IV) and in-*
14 *serting the following:*

15 *“(IV) the emergency health secu-*
16 *rity threat or threats such counter-*
17 *measure procurement is intended to*
18 *address, including—*

19 *“(aa) whether such procure-*
20 *ment is consistent with meeting*
21 *emergency health security needs*
22 *associated with such threat or*
23 *threats; and*

24 *“(bb) in the case of a coun-*
25 *termeasure that addresses a bio-*

1 *logical agent, whether such agent*
2 *has an increased likelihood to be-*
3 *come resistant to, more resistant*
4 *to, or evade, such countermeasure*
5 *relative to other available medical*
6 *countermeasures;”;*

7 *(B) in paragraph (3)—*

8 *(i) in subparagraph (B), by striking*
9 *“are followed, regularly reviewed, and up-*
10 *dated with respect to such stockpile” and*
11 *inserting “with respect to such stockpile are*
12 *followed, regularly reviewed, and updated to*
13 *reflect best practices”;*

14 *(ii) in subparagraph (I), by inserting*
15 *“, through a standard operating procedure,”*
16 *after “ensure”;*

17 *(iii) by redesignating subparagraphs*
18 *(H) through (K) as subparagraphs (I)*
19 *through (L), respectively; and*

20 *(iv) by inserting after subparagraph*
21 *(G) the following:*

22 *“(H) utilize tools to enable the timely and*
23 *accurate tracking of the contents of the stockpile*
24 *throughout the deployment of such contents, in-*
25 *cluding tracking of the location and geographic*

1 *distribution and utilization of such contents;*”;
 2 *and*

3 *(C) in paragraph (5)(B), in the matter pre-*
 4 *ceding clause (i), by inserting “, which may ac-*
 5 *company the review required under paragraph*
 6 *(2),” after “Representatives a report”;*

7 *(2) in subsection (c)(2)(C)—*

8 *(A) by striking “promptly”; and*

9 *(B) by inserting “, not later than 60 days*
 10 *after each such determination,”;*

11 *(3) in subsection (f)(1), by striking*
 12 *“\$610,000,000 for each of fiscal years 2019 through*
 13 *2021, and \$750,000,000 for each of fiscal years 2022*
 14 *and 2023” and inserting “\$965,000,000 for each of*
 15 *fiscal years 2024 through 2028”; and*

16 *(4) in subsection (g)(1), by striking “2019*
 17 *through 2028” and inserting “2024 through 2033”.*

18 **SEC. 207. MEDICAL COUNTERMEASURES FOR VIRAL**

19 **THREATS WITH PANDEMIC POTENTIAL.**

20 *Section 319L of the Public Health Service Act (42*
 21 *U.S.C. 247d–7e) is amended—*

22 *(1) in subsection (c)(4)—*

23 *(A) in subparagraph (D), by amending*
 24 *clause (iii) to read as follows:*

1 “(iii) research to promote strategic ini-
2 tiatives, such as—

3 “(I) rapid diagnostics;

4 “(II) broad spectrum
5 antimicrobials;

6 “(III) medical countermeasures
7 for virus families that have significant
8 potential to cause a pandemic, includ-
9 ing such countermeasures that take ei-
10 ther pathogen-specific or broad spec-
11 trum approaches; and

12 “(IV) technologies to improve the
13 production and use of medical counter-
14 measures, which may include vaccine-
15 manufacturing technologies, dose-spar-
16 ing technologies, efficacy-increasing
17 technologies, platform technologies,
18 technologies to administer counter-
19 measures, and technologies to improve
20 storage and transportation of counter-
21 measures.”; and

22 (B) in subparagraph (F)(ii), by inserting
23 “or priority virus families and other viral
24 pathogens that pose a threat due to their signifi-

1 cant potential to cause a pandemic,” after “pan-
2 demic influenza,”;

3 (2) in subsection (d)(2), by striking
4 “\$611,700,000 for each of fiscal years 2019 through
5 2023” and inserting “\$950,000,000 for each of fiscal
6 years 2024 through 2028”; and

7 (3) in subsection (e)(1), by amending subpara-
8 graph (D) to read as follows:

9 “(D) SUNSET.—This paragraph shall cease
10 to have force or effect after September 30, 2028.”.

11 **SEC. 208. PUBLIC HEALTH EMERGENCY MEDICAL COUNTER-**
12 **MEASURES ENTERPRISE.**

13 Section 2811–1(c) of the Public Health Service Act (42
14 U.S.C. 300hh–10a(c)) is amended—

15 (1) in paragraph (1)—

16 (A) by redesignating subparagraph (D) as
17 subparagraph (E); and

18 (B) by inserting after subparagraph (C) the
19 following:

20 “(D) Assist the Secretary in developing
21 strategies for appropriate and evidence-based al-
22 location and distribution of countermeasures to
23 jurisdictions, in a manner that supports the
24 availability and use of such countermeasures, for

1 (2) *research from relevant external stakeholders*
2 *related to evidence-based or evidence-informed strate-*
3 *gies and best practices to effectively communicate and*
4 *disseminate such information; and*

5 (3) *strategies to improve communication and*
6 *dissemination of scientific and evidence-based public*
7 *health information to the public and to improve com-*
8 *munication between Federal, State, local, and Tribal*
9 *health officials.*

10 (c) *COMPOSITION.—The Advisory Committee shall be*
11 *composed of—*

12 (1) *appropriate Federal officials, appointed by*
13 *the Secretary, who shall serve as nonvoting members;*
14 *and*

15 (2) *individuals, appointed by the Secretary, rep-*
16 *resenting a variety of States and rural and urban*
17 *areas, and each of whom that has—*

18 (A) *expertise in public health, including*
19 *through experience in State, local, and Tribal*
20 *health departments, medicine, communications,*
21 *related technology, psychology, mental health and*
22 *substance use disorders, or national security;*

23 (B) *experience in leading community out-*
24 *reach; or*

1 (C) expertise in other areas, as the Sec-
2 retary determines appropriate.

3 (d) *DISSEMINATION.*—The Secretary shall review the
4 recommendations of the Advisory Committee and, not later
5 than 180 days after receipt of the report under subsection
6 (b), shall submit to the Committee on Health, Education,
7 Labor, and Pensions of the Senate and the Committee on
8 Energy and Commerce of the House of Representatives a
9 report describing any actions planned by the Secretary re-
10 lated to this section.

11 (e) *TERMINATION.*—The Advisory Committee shall ter-
12 minate 2 years after the date of enactment of this Act.

13 **SEC. 210. FELLOWSHIP AND TRAINING PROGRAMS.**

14 Section 317G of the Public Health Service Act (42
15 U.S.C. 247b–8) is amended—

16 (1) by striking “The Secretary,” and inserting
17 the following:

18 “(a) *IN GENERAL.*—The Secretary,”; and

19 (2) by adding at the end the following:

20 “(b) *NONCOMPETITIVE CONVERSION.*—

21 “(1) *IN GENERAL.*—The Secretary may non-
22 competitively convert an individual who has com-
23 pleted an epidemiology, surveillance, or laboratory
24 fellowship or training program under subsection (a)
25 to a career-conditional appointment without regard

1 to the provisions of subchapter I of chapter 33 of title
2 5, United States Code, provided that such individual
3 meets qualification requirements for the appoint-
4 ment.”.

5 **SEC. 211. ASSESSMENT OF COVID-19 MITIGATION POLICIES.**

6 (a) *GAO STUDY.*—The Comptroller General of the
7 United States shall conduct a study on the economic impact
8 and health outcomes associated with the response to the
9 COVID-19 pandemic in the United States. Such study
10 shall include—

11 (1) a summary of strategies used by local govern-
12 mental entities, States, and the Federal Government
13 to contain and mitigate the spread of COVID-19 dur-
14 ing the public health emergency declared under sec-
15 tion 319 of the Public Health Service Act (42 U.S.C.
16 247d) on January 31, 2020, including—

17 (A) limitations on large gatherings of peo-
18 ple;

19 (B) the closure of schools, businesses, houses
20 of worship, and other facilities;

21 (C) masking policies;

22 (D) testing policies; and

23 (E) vaccination policies;

24 (2) an analysis and review of the scientific evi-
25 dence related to the effectiveness of such strategies in

1 “(j) *EMERGING PATHOGENS PREPAREDNESS PRO-*
2 *GRAM.*—

3 “(1) *IN GENERAL.*—*The Secretary shall establish*
4 *a program to facilitate the development, review, licen-*
5 *sure, approval, and clearance of countermeasures, and*
6 *products that could potentially be countermeasures,*
7 *under the jurisdiction of the Center for Biologics*
8 *Evaluation and Research.*

9 “(2) *ACTIVITIES.*—*The activities of the program*
10 *established under paragraph (1) may include, either*
11 *directly or by grant, contract, or cooperative agree-*
12 *ment, the following:*

13 “(A) *Any activities described in subsection*
14 *(b).*

15 “(B) *Activities to advance scientific re-*
16 *search related to the development of tools, stand-*
17 *ards, and approaches to assess the safety, effi-*
18 *cacy, quality, and performance of counter-*
19 *measures.*

20 “(C) *Activities to maintain or enhance sur-*
21 *veillance programs that monitor counter-*
22 *measures.*

23 “(D) *Activities to help ensure blood safety*
24 *and availability.*

1 “(E) *Prioritizing the research and develop-*
2 *ment of platform vaccine technologies to support*
3 *an emergency use authorization request under*
4 *section 564 or an application under section*
5 *351(a) of the Public Health Service Act.*

6 “(F) *Such other activities as the Secretary*
7 *determines necessary or appropriate.*

8 “(3) *RULE OF CONSTRUCTION.—Nothing in this*
9 *subsection shall be construed to alter the authority of*
10 *the Secretary to license, approve, clear, or authorize*
11 *countermeasures, including biological products, pur-*
12 *suant to section 351 of the Public Health Service Act*
13 *or section 505 or 564 of this Act, including standards*
14 *of evidence and applicable conditions for licensure,*
15 *approval, clearance, or authorization.”.*

16 “(b) *AUTHORIZATION OF APPROPRIATIONS.—To carry*
17 *out subsection (j) of section 565 of the Federal Food, Drug,*
18 *and Cosmetic Act (21 U.S.C. 360bbb–4), as added by sub-*
19 *section (a), there are authorized to be appropriated such*
20 *sums as may be necessary for each of fiscal years 2024*
21 *through 2028.*

1 **TITLE III—ADDRESSING THE**
 2 **NEEDS OF ALL INDIVIDUALS**

3 **SEC. 301. TRANSITION OF CERTAIN COUNTERMEASURES**
 4 **BETWEEN COMPENSATION PROGRAMS.**

5 (a) *TREATMENT OF CERTAIN INELIGIBLE REQUESTS*
 6 *RELATED TO COVID–19 COUNTERMEASURES.*—

7 (1) *REQUESTS INITIALLY SUBMITTED UNDER*
 8 *CICP.*—

9 (A) *IN GENERAL.*—*In the case of a request*
 10 *for compensation submitted under section 319F–*
 11 *4 of the Public Health Service Act (42 U.S.C.*
 12 *247d–6e) for an injury or death related to a*
 13 *COVID–19 vaccine that the Secretary determines*
 14 *to be ineligible pursuant to subparagraph (B) of*
 15 *such section 319F–4(b)(4), as added by sub-*
 16 *section (b)(1), the Secretary shall, not later than*
 17 *30 days after such determination, notify the in-*
 18 *dividual submitting the request of such deter-*
 19 *mination.*

20 (B) *SUBMISSION OF PETITION.*—*An indi-*
 21 *vidual who receives a notification described in*
 22 *subparagraph (A) shall be eligible to submit a*
 23 *petition to the United States Court of Federal*
 24 *Claims under section 2111 of the Public Health*
 25 *Service Act (42 U.S.C. 300aa–11) with respect to*

1 *the same vaccine administration claimed in the*
 2 *request submitted under section 319F-4 of such*
 3 *Act (42 U.S.C. 247d-6e), provided that such pe-*
 4 *tion is submitted not later than the later of—*

5 *(i) 1 year after receiving such notifica-*
 6 *tion under subparagraph (A); or*

7 *(ii) the last date on which the indi-*
 8 *vidual otherwise would be eligible to submit*
 9 *a petition relating to such injury, as speci-*
 10 *fied in section 2116 of the Public Health*
 11 *Service Act (42 U.S.C. 300aa-16).*

12 (C) *ELIGIBILITY.*—*To be eligible to submit*
 13 *a petition in accordance with subparagraph (B),*
 14 *the petitioner shall have submitted the request for*
 15 *compensation under section 319F-4 of the Public*
 16 *Health Service Act (42 U.S.C. 247d-6e) that was*
 17 *determined to be ineligible not later than the*
 18 *deadline for filing a petition under section 2116*
 19 *of the Public Health Service Act (42 U.S.C.*
 20 *300aa-16) that applies with respect to the ad-*
 21 *ministration of such vaccine.*

22 (2) *REQUESTS INITIALLY SUBMITTED UNDER*
 23 *VICP.*—

24 (A) *IN GENERAL.*—*If a special master de-*
 25 *termines that—*

1 (i) a petition submitted under section
2 2111 of the Public Health Service Act (42
3 U.S.C. 300aa-11) related to a COVID-19
4 vaccine is ineligible for the National Vac-
5 cine Injury Compensation Program under
6 subtitle 2 of title XXI of the Public Health
7 Service Act (42 U.S.C. 300aa-10 et seq.) be-
8 cause it relates to a vaccine administered at
9 a time when the vaccine was not included
10 in the Vaccine Injury Table under section
11 2114 of such Act (42 U.S.C. 300aa-14); and

12 (ii) the vaccine was administered when
13 it was a covered countermeasure subject to
14 a declaration under section 319F-3(b) of
15 such Act (42 U.S.C. 247d-6d(b)),

16 the special master shall, not later than 30 days
17 after such determination, notify the petitioner of
18 such determination.

19 (B) *SUBMISSION OF REQUEST.*—An indi-
20 vidual who receives a notification described in
21 subparagraph (A) shall be eligible to submit a
22 request for compensation under section 319F-
23 4(b) of the Public Health Service Act (42 U.S.C.
24 247d-6e(b)) with respect to the same vaccine ad-
25 ministration claimed in the petition submitted

1 *under section 2111 of such Act (42 U.S.C.*
2 *300aa-11)*—

3 *(i) not later than 1 year after receiving*
4 *such notification; or*

5 *(ii) in the case that the notification is*
6 *issued after judicial review of the petition*
7 *under subsection (e) or (f) of section 2112 of*
8 *such Act (42 U.S.C. 300aa-12), not later*
9 *than 1 year after the decision of the United*
10 *States Court of Federal Claim or the man-*
11 *date is issued by the United States Court of*
12 *Appeals for the Federal Circuit pursuant to*
13 *such subsection (e) or (f).*

14 (C) *ELIGIBILITY.*—*To be eligible to submit*
15 *a request for compensation in accordance with*
16 *subparagraph (B), the individual submitting the*
17 *request shall have submitted the petition under*
18 *section 2111 of the Public Health Service Act (42*
19 *U.S.C. 300aa-11) that was determined to be in-*
20 *eligible not later than 1 year after the date of*
21 *administration of the vaccine.*

22 (b) *CHANGES TO CERTAIN PROGRAMS.*—

23 (1) *CICP.*—*Section 319F-4 of the Public Health*
24 *Service Act (42 U.S.C. 247d-6e) is amended—*

25 (A) *in subsection (b)(4)—*

1 (i) by striking “Except as provided”
2 and inserting the following:

3 “(A) *IN GENERAL.—Except as provided*”;
4 and

5 (ii) by adding at the end the following:

6 “(B) *EXCLUSION OF INJURIES CAUSED BY*
7 *VACCINES ON THE VACCINE INJURY TABLE.—Not-*
8 *withstanding any other provision of this section,*
9 *no individual may be eligible for compensation*
10 *under this section with respect to a vaccine that,*
11 *at the time it was administered, was included in*
12 *the Vaccine Injury Table under section 2114.*”;
13 and

14 (B) in subsection (d)(3)—

15 (i) by striking “This section” and in-
16 serting the following:

17 “(A) *IN GENERAL.—This section*”; and

18 (ii) by adding at the end the following:

19 “(B) *EXHAUSTION OF REMEDIES.—A cov-*
20 *ered individual shall not be considered to have*
21 *exhausted remedies as described in paragraph*
22 *(1), nor be eligible to seek remedy under section*
23 *319F–3(d), unless such individual has provided*
24 *to the Secretary all supporting documentation*

1 *necessary to facilitate the determinations re-*
2 *quired under subsection (b)(4).”.*

3 (2) *VICP.—Title XXI of the Public Health Serv-*
4 *ice Act (42 U.S.C. 300aa–1 et seq.) is amended—*

5 (A) *in section 2111(a)(2)(A) (42 U.S.C.*
6 *300aa–11(a)(2)(A)), in the matter preceding*
7 *clause (i), by inserting “containing the informa-*
8 *tion required under subsection (c)” after “unless*
9 *a petition”;*

10 (B) *in section 2112(d) (42 U.S.C. 300aa–*
11 *12(d))—*

12 (i) *by adding at the end of paragraph*
13 (1) *the following: “Such designation shall*
14 *not occur until the petitioner has filed all*
15 *materials required under section 2111(c).”;*
16 *and*

17 (ii) *in paragraph (3)(A)(ii), by strik-*
18 *ing “the petition was filed” and inserting*
19 *“on which the chief special master makes*
20 *the designation pursuant to paragraph (1)”;*

21 (C) *in section 2114(e) (42 U.S.C. 300aa–*
22 *14(e))—*

23 (i) *in paragraph (2), in the matter*
24 *preceding subparagraph (A), by striking “2*
25 *years” and inserting “6 months”; and*

1 (ii) by adding at the end the following:

2 “(4) *LICENSURE REQUIREMENT.*—Notwith-
3 standing paragraphs (2) and (3), the Secretary may
4 not revise the Vaccine Injury Table to include a vac-
5 cine for which the Centers for Disease Control and
6 Prevention has issued a recommendation for routine
7 use in children or pregnant women until at least one
8 application for such vaccine has been approved under
9 section 351. Upon such revision of the Vaccine Injury
10 Table, all vaccines to prevent the same infectious dis-
11 ease, including vaccines authorized under emergency
12 use pursuant to section 564 of the Federal Food,
13 Drug, and Cosmetic Act, shall be considered included
14 in the Vaccine Injury Table.”; and

15 (D) in section 2116 (42 U.S.C. 300aa-16),
16 by adding at the end the following:

17 “(d) *CLARIFICATION.*—Notwithstanding subsections
18 (a) and (b), an injury or death related to a vaccine admin-
19 istered at a time when the vaccine was a covered counter-
20 measure subject to a declaration under section 319F-3(b)
21 shall not be eligible for compensation under the Program.”.

1 **SEC. 302. ACCELERATING INJURY COMPENSATION PRO-**
2 **GRAM ADMINISTRATION AND ENSURING PRO-**
3 **GRAM INTEGRITY.**

4 (a) *PETITIONS FOR COMPENSATION.*—Section
5 2111(a)(2)(A)(i) of the Public Health Service Act (42
6 U.S.C. 300aa–11(a)(2)(A)(i)) is amended—

7 (1) in subclause (I), by striking “, and” and in-
8 serting a semicolon;

9 (2) in subclause (II)—

10 (A) by moving the margin 2 ems to the
11 right; and

12 (B) by striking “, or” and inserting “;
13 and”; and

14 (3) by adding at the end the following:

15 “(III) the judgment described in subclause
16 (I) does not result from a petitioner’s motion to
17 dismiss the case; or”.

18 (b) *DETERMINATION OF GOOD FAITH.*—Section
19 2115(e)(1) of the Public Health Service Act (42 U.S.C.
20 300aa–15(e)(1)) is amended by adding at the end the fol-
21 lowing: “When making a determination of good faith under
22 this paragraph, the special master or court may consider
23 whether the petitioner demonstrated an intention to obtain
24 compensation on such petition and was not merely seeking
25 to satisfy the exhaustion requirement under section
26 2121(b).”.

1 **SEC. 303. COMPENSATION FOR INJURIES RELATING TO THE**
2 **PUBLIC HEALTH EMERGENCY CAUSED BY**
3 **SARS-COV-2.**

4 (a) *IN GENERAL.*—*With respect to claims filed under*
5 *the Countermeasures Injury Compensation Program (re-*
6 *ferred to in this section as “the Program”) under section*
7 *319F–4 of the Public Health Service Act (42 U.S.C. 247d–*
8 *6e) alleging a covered injury caused by the administration*
9 *or use of a covered countermeasure pursuant to a declara-*
10 *tion under section 319F–3(b) of such Act (42 U.S.C. 247d–*
11 *6d(b)) relating to COVID–19, the following shall apply:*

12 (1) *Notwithstanding the filing deadline applica-*
13 *ble under such section 319F–4, the claim shall be filed*
14 *within 3 years of the administration or use of the*
15 *covered countermeasure, or 1 year after the date of en-*
16 *actment of this Act, whichever is later, and, if a*
17 *claim filed under the Program with respect to such*
18 *administration or use was filed before the date of en-*
19 *actment of this Act and denied on the basis of having*
20 *not been filed within the time period required under*
21 *subsection (b)(4) of such section 319F–4, such claim*
22 *may be refiled pursuant to this paragraph.*

23 (2) *With respect to a claim relating to the ad-*
24 *ministration of a COVID–19 vaccine, such a claim*
25 *may be filed under the Program only if the adminis-*
26 *tration of such vaccine occurred prior to the addition*

1 of the vaccine to the Vaccine Injury Table under sec-
2 tion 2114 of the Public Health Service Act (42 U.S.C.
3 300aa-14).

4 (3) Not later than 9 months after the date of en-
5 actment of this Act, the Secretary of Health and
6 Human Services shall publish a notice of proposed
7 rulemaking establishing a covered countermeasure in-
8 jury table pursuant to section 319F-4(b)(5) of the
9 Public Health Service Act (42 U.S.C. 247d-6e(b)(5)).

10 (b) NASEM REPORT.—The Secretary of Health and
11 Human Services shall seek to enter into a contract with
12 the National Academies of Sciences, Engineering, and Med-
13 icine under which such National Academies shall report,
14 not later than 3 years after the date of enactment of this
15 Act, on the Countermeasures Injury Compensation Program
16 under section 319F-4 of the Public Health Service Act (42
17 U.S.C. 247d-6e), including recommendations to improve
18 the administration of such program and whether Congress
19 should adjust the compensation payments available under
20 such program.

21 **SEC. 304. REVIEW OF REGULATIONS.**

22 The Secretary of Health and Human Services shall up-
23 date regulations, as needed for purposes of carrying out the
24 amendments made by sections 301 and 302.

1 **SEC. 305. SUPPORTING INDIVIDUALS WITH DISABILITIES,**
2 **OLDER ADULTS, AND OTHER AT-RISK INDI-**
3 **VIDUALS DURING EMERGENCY RESPONSES.**

4 (a) *TECHNICAL ASSISTANCE CENTERS ON AT-RISK IN-*
5 *DIVIDUALS AND DISASTERS.*—

6 (1) *IN GENERAL.*—*The Secretary of Health and*
7 *Human Services (referred to in this section as the*
8 *“Secretary”)* may, through grants, contracts, or coop-
9 *erative agreements to eligible entities, establish re-*
10 *search, training, and technical assistance centers to*
11 *provide appropriate information, training, and tech-*
12 *nical assistance to States, localities, Tribes, and other*
13 *applicable entities related to addressing the unique*
14 *needs and considerations of at-risk individuals, as de-*
15 *fin ed in section 2802(b)(4) of the Public Health Serv-*
16 *ice Act (42 U.S.C. 300hh–1(b)(4)), in the event of a*
17 *public health emergency declared by the Secretary*
18 *pursuant to section 319 of the Public Health Service*
19 *Act (42 U.S.C. 247d).*

20 (2) *RESPONSIBILITIES OF THE CENTERS.*—*The*
21 *centers established under paragraph (1) shall conduct*
22 *activities for the purposes of—*

23 (A) *developing, identifying, evaluating, and*
24 *disseminating evidence-based or evidence-in-*
25 *formed strategies to improve health and other re-*
26 *lated outcomes for at-risk individuals related to*

1 *public health emergencies, including by address-*
2 *ing such unique needs and considerations in car-*
3 *rying out public health and medical activities to*
4 *prepare for, respond to, and recover from, such*
5 *public health emergencies; and*

6 *(B) assisting applicable entities in the im-*
7 *plementation of such evidence-based strategies,*
8 *including through subawards.*

9 *(3) PRIORITY.—In awarding grants for activities*
10 *described in this subsection, the Secretary shall give*
11 *priority to eligible entities with demonstrated exper-*
12 *tise in, and ability to carry out, the activities de-*
13 *scribed in paragraph (2).*

14 *(4) CONSULTATION.—In carrying out activities*
15 *under paragraph (2), the centers established under*
16 *paragraph (1) shall take into consideration relevant*
17 *findings and recommendations of, and, as appro-*
18 *priate, consult with, the National Advisory Com-*
19 *mittee on Individuals with Disabilities and Disasters*
20 *established under section 2811C of the Public Health*
21 *Service Act (42 U.S.C. 300hh–10d), the National Ad-*
22 *visory Committee on Children and Disasters under*
23 *section 2811A of such Act (42 U.S.C. 300hh–10b),*
24 *and the National Advisory Committee on Seniors and*

1 *Disasters under section 2811B of such Act (42 U.S.C.*
2 *300hh–10c).*

3 (5) *REPORTS.*—*Not later than 2 years after the*
4 *date of enactment of this Act and every 2 years there-*
5 *after, the Secretary shall submit to the Committee on*
6 *Health, Education, Labor, and Pensions of the Senate*
7 *and the Committee on Energy and Commerce of the*
8 *House of Representatives a report describing the ac-*
9 *tivities carried out under this subsection during the*
10 *preceding 2 fiscal years.*

11 (6) *SUNSET.*—*This subsection shall cease to have*
12 *force or effect on September 30, 2028.*

13 (b) *CRISIS STANDARDS OF CARE.*—*Not later than 2*
14 *years after the date of enactment of this Act, the Secretary,*
15 *acting through the Director of the Office for Civil Rights*
16 *of the Department of Health and Human Services, shall*
17 *issue guidance to States and localities on the development*
18 *or modification of State and local crisis standards of care*
19 *for use during the response to a public health emergency*
20 *declared by the governor of a State or by the Secretary*
21 *under section 319 of the Public Health Service Act (42*
22 *U.S.C. 247d), or a major disaster or emergency declared*
23 *by the President under section 401 or 501, respectively, of*
24 *the Robert T. Stafford Disaster Relief and Emergency As-*
25 *sistance Act (42 U.S.C. 5170, 5191) to ensure that such*

1 *standards of care are consistent with the nondiscrimination*
 2 *requirements of section 504 of the Rehabilitation Act of*
 3 *1973 (29 U.S.C. 794), title II of the Americans with Dis-*
 4 *abilities Act of 1990 (42 U.S.C. 12131 et seq.), and the Age*
 5 *Discrimination Act of 1975 (42 U.S.C. 6101 et seq.).*

6 **SEC. 306. NATIONAL ADVISORY COMMITTEES.**

7 (a) *NATIONAL ADVISORY COMMITTEE ON CHILDREN*
 8 *AND DISASTERS.*—*Section 2811A of the Public Health*
 9 *Service Act (42 U.S.C. 300hh–10b) is amended—*

10 (1) *in subsection (c)—*

11 (A) *by striking “may provide advice” and*
 12 *inserting the following: “may provide—*

13 *“(1) advice”;*

14 (B) *by striking the period and inserting “;*
 15 *and”;* and

16 (C) *by adding at the end the following:*

17 *“(2) recommendations to the Director of the Of-*
 18 *fice of Pandemic Preparedness and Response Policy*
 19 *and to Congress with respect to the public health and*
 20 *emergency preparedness needs of children.”; and*

21 (2) *in subsection (g), by striking “2023” and in-*
 22 *serting “2028”.*

23 (b) *NATIONAL ADVISORY COMMITTEE ON SENIORS AND*
 24 *DISASTERS.*—*Section 2811B of the Public Health Service*
 25 *Act (42 U.S.C. 300hh–10c) is amended—*

1 (1) *in subsection (c)—*

2 (A) *by striking “may provide advice” and*
3 *inserting the following: “may provide—*
4 *“(1) advice”;*

5 (B) *by striking the period and inserting “;*
6 *and”;* *and*

7 (C) *by adding at the end the following:*

8 “*(2) recommendations to the Director of the Of-*
9 *fice of Pandemic Preparedness and Response Policy*
10 *and to Congress with respect to the public health and*
11 *emergency preparedness needs of seniors.”;*

12 (2) *in subsection (d)—*

13 (A) *in paragraph (1), by striking “17 mem-*
14 *bers” and inserting “25 members”;* *and*

15 (B) *in paragraph (2)—*

16 (i) *in subparagraph (J), by striking*
17 *“2” and inserting “3”;*

18 (ii) *in subparagraph (K), by striking*
19 *“2” and inserting “3”;*

20 (iii) *by redesignating subparagraphs*
21 *(K) and (L) as subparagraphs (L) and (M),*
22 *respectively; and*

23 (iv) *by inserting after subparagraph*
24 *(J) the following:*

1 “(K) *At least 2 non-Federal health care pro-*
2 *essionals with expertise in gerontology.*”; and

3 (3) *by amending subsection (g) to read as fol-*
4 *lows:*

5 “(g) *SUNSET.—The Advisory Committee shall termi-*
6 *nate on September 30, 2028.*”.

7 (c) *NATIONAL ADVISORY COMMITTEE ON INDIVIDUALS*
8 *WITH DISABILITIES AND DISASTERS.—Section 2811C of*
9 *the Public Health Service Act (42 U.S.C. 300hh–10d) is*
10 *amended—*

11 (1) *by redesignating subsections (c) through (g)*
12 *as subsections (d) through (h), respectively;*

13 (2) *by inserting after subsection (b) the fol-*
14 *lowing:*

15 “(c) *ADDITIONAL DUTIES.—The Advisory Committee*
16 *may provide—*

17 “(1) *advice and recommendations to the Sec-*
18 *retary and to Congress with respect to individuals*
19 *with disabilities and the medical and public health*
20 *grants and cooperative agreements as applicable to*
21 *preparedness and response activities under this title*
22 *and title III; and*

23 “(2) *recommendations to the Director of the Of-*
24 *fice of Pandemic Preparedness and Response Policy*
25 *and to Congress with respect to the public health and*

1 *emergency preparedness needs of individuals with dis-*
2 *abilities.”;*

3 *(3) in subsection (d), as so redesignated—*

4 *(A) in paragraph (1), by striking “17 mem-*
5 *bers” and inserting “25 members”;*

6 *(B) in paragraph (2)—*

7 *(i) by striking subparagraphs (K)*
8 *through (M); and*

9 *(ii) by inserting after subparagraph*
10 *(J) the following:*

11 *“(K) 15 non-Federal members (at least 4 of*
12 *whom shall be individuals with disabilities) from*
13 *diverse backgrounds, including the following:*

14 *“(i) One representative from each of*
15 *the following:*

16 *“(I) A nongovernmental organiza-*
17 *tion that provides disaster prepared-*
18 *ness and response services.*

19 *“(II) A community-based organi-*
20 *zation that represents individuals with*
21 *multiple types of disabilities.*

22 *“(III) A State-based organization*
23 *that represents individuals with mul-*
24 *tiple types of disabilities.*

1 “(IV) A national organization
2 that represents individuals with mul-
3 tiple types of disabilities.

4 “(V) A national organization that
5 represents older adults.

6 “(VI) An organization that pro-
7 vides relevant housing services, includ-
8 ing during the response to, and recov-
9 ery from, disasters.

10 “(VII) An organization that rep-
11 resents disabled veterans.

12 “(ii) Four individuals with geographi-
13 cally diverse expertise in emergency man-
14 agement.

15 “(iii) Two non-Federal health care
16 professionals with expertise in disability ac-
17 cessibility before, during, and after disas-
18 ters, medical and mass care disaster plan-
19 ning, preparedness, response, or recovery.”;
20 and

21 (C) by adding at the end the following:

22 “(3) CONSIDERATION.—In appointing members,
23 including the Chair, to the Committee under this sub-
24 section, the Secretary may give consideration to dis-
25 ability status.”; and

1 (4) by amending subsection (h), as so redesign-
2 nated, to read as follows:

3 “(h) *SUNSET.*—*The Advisory Committee shall termi-*
4 *nate on September 30, 2028.*”.

5 **SEC. 307. RESEARCH AND COORDINATION OF ACTIVITIES**
6 **CONCERNING THE LONG-TERM HEALTH EF-**
7 **FFECTS OF SARS-COV-2 INFECTION.**

8 (a) *IN GENERAL.*—*The Secretary of Health and*
9 *Human Services (referred to in this section as the “Sec-*
10 *retary”)* shall, as appropriate—

11 (1) *coordinate activities among relevant Federal*
12 *departments and agencies with respect to addressing*
13 *the long-term health effects of SARS-CoV-2 infection,*
14 *which may include conditions that arise as a result*
15 *of such infection;*

16 (2) *continue to conduct or support basic, clin-*
17 *ical, epidemiological, behavioral, and translational*
18 *research and public health surveillance related to the*
19 *pathogenesis, prevention, diagnosis, and treatment of*
20 *the long-term health effects of SARS-CoV-2 infection*
21 *and re-infection, which may include conditions and*
22 *any effects on development, cognition, and neural*
23 *structure and function that arise as a result of such*
24 *infection; and*

1 (3) *consistent with the findings of studies and re-*
2 *search under paragraph (2), in consultation with*
3 *health and public health professional associations, sci-*
4 *entific and medical researchers, and other relevant ex-*
5 *perts, develop and inform recommendations, guidance,*
6 *and educational materials on the long-term effects of*
7 *SARS-CoV-2 infection, which may include condi-*
8 *tions that arise as a result of such infection, and pro-*
9 *vide such recommendations, guidance, and edu-*
10 *cational materials to health care providers and the*
11 *general public.*

12 (b) *CONSIDERATIONS.—In conducting or supporting*
13 *research under this section, the Secretary shall consider the*
14 *diversity of research participants or cohorts to ensure inclu-*
15 *sion of a broad range of participants, as applicable and*
16 *appropriate.*

17 (c) *ADDITIONAL ACTIVITIES.—The Secretary may—*

18 (1) *acting through the Director of the Agency for*
19 *Healthcare Research and Quality, conduct or support*
20 *research related to—*

21 (A) *the improvement of health care delivery*
22 *for individuals experiencing long-term health ef-*
23 *fects of SARS-CoV-2, which may include condi-*
24 *tions that arise as a result of such infection;*

1 (B) the identification of any trends associ-
2 ated with differences in diagnosis and treatment
3 of the long-term health effects of SARS-CoV-2
4 infection and related conditions; and

5 (C) the development or identification of
6 tools and strategies to help health care entities
7 and providers care for such populations, which
8 may include addressing any differences identi-
9 fied pursuant to subparagraph (B);

10 (2) publicly disseminate the results of such re-
11 search; and

12 (3) establish a primary care technical assistance
13 initiative to convene primary care providers and or-
14 ganizations, which may include support for con-
15 tinuing training and education for such providers, as
16 applicable and appropriate, in order to collect and
17 disseminate best practices related to the care of indi-
18 viduals with long-term health effects of SARS-CoV-
19 2 infection, which may include conditions that arise
20 as a result of such infection.

21 (d) ANNUAL REPORTS.—Not later than 1 year after
22 the date of enactment of this Act, and annually thereafter
23 for the next 4 years, the Secretary shall prepare and submit
24 a report to the Committee on Health, Education, Labor,
25 and Pensions of the Senate and the Committee on Energy

1 *and Commerce of the House of Representatives regarding*
 2 *an overview of the research conducted or supported under*
 3 *this section and any relevant findings. Such reports may*
 4 *include information about how the research and relevant*
 5 *findings under this section relate to other research efforts*
 6 *supported by other public or private entities.*

7 *(e) PUBLIC AVAILABILITY OF INFORMATION.—In mak-*
 8 *ing information or reports publicly available under this sec-*
 9 *tion, the Secretary shall take into consideration the delivery*
 10 *of such information in a manner that takes into account*
 11 *the range of communication needs of the intended recipi-*
 12 *ents, including at-risk individuals.*

13 **SEC. 308. NATIONAL ACADEMIES STUDY ON PRIZES.**

14 *(a) IN GENERAL.—Not later than 90 days after the*
 15 *date of enactment of this Act, the Secretary of Health and*
 16 *Human Services shall seek to enter into an agreement with*
 17 *the National Academies of Sciences, Engineering, and Med-*
 18 *icine (referred to in this section as the “National Acad-*
 19 *emies”)* to conduct a study to examine—

20 *(1) alternative models for directly funding, or*
 21 *stimulating investment in, biomedical research and*
 22 *development that delink research and development*
 23 *costs from the prices of drugs, including the progres-*
 24 *sive replacement of patents and regulatory*
 25 *exclusivities on new drugs with a combination of ex-*

1 *panded support for research and innovation prizes to*
2 *reward the successful development of drugs or achieve-*
3 *ment of related milestones;*

4 (2) *the dollar amount of innovation prizes for*
5 *different stages of research and development of dif-*
6 *ferent classes or types of drugs, and total annual*
7 *funding, that would be necessary to stimulate invest-*
8 *ment sufficient to achieve such successful drug devel-*
9 *opment and related milestones;*

10 (3) *the relative effectiveness and efficiency of*
11 *such alternative models in stimulating innovation,*
12 *compared to the status quo that includes patents and*
13 *regulatory exclusivities;*

14 (4) *strategies to implement such alternative mod-*
15 *els described in paragraph (1), including a phased*
16 *transition; and*

17 (5) *the anticipated economic and societal im-*
18 *pacts of such alternative models, including an assess-*
19 *ment of impact on—*

20 (A) *the number and variety of new drugs*
21 *that would be developed, approved, and marketed*
22 *in the United States, including such new drugs*
23 *intended to prevent, diagnose, or treat a rare*
24 *disease or condition;*

1 (B) the rate at which new drugs would be
2 developed, approved, and marketed in the United
3 States;

4 (C) access to medication;

5 (D) health outcomes;

6 (E) average lifespan and disease burden in
7 the United States;

8 (F) the number of manufacturers that
9 would be seeking approval for a drug or bringing
10 a drug to market for the first time;

11 (G) Federal discretionary and mandatory
12 spending; and

13 (H) public and private insurance markets.

14 (b) *AUTHORIZATION OF APPROPRIATIONS.*—To carry
15 out this section, there is authorized to be appropriated
16 \$3,000,000 for fiscal year 2024.

17 (c) *REQUIREMENTS.*—In conducting the study pursu-
18 ant to subsection (a), the National Academies shall hold not
19 fewer than 2 public listening sessions to solicit feedback
20 from interested parties, including representatives of aca-
21 demia, professional societies, patient advocates, public
22 health organizations, relevant Federal departments and
23 agencies, drug developers, representatives of other relevant
24 industries, and subject matter experts.

1 (d) *REPORT.*—Not later than 2 years after the date
 2 of enactment of this Act, the National Academies shall sub-
 3 mit to the Committee on Health, Education, Labor, and
 4 Pensions and the Committee on Appropriations of the Sen-
 5 ate and the Committee on Energy and Commerce and the
 6 Committee on Appropriations of the House of Representa-
 7 tives a report on the study conducted pursuant to subsection
 8 (a).

9 **TITLE IV—STRENGTHENING**
 10 **BIOSECURITY**

11 **SEC. 401. TREATMENT OF GENETIC VARIANTS AND SYN-**
 12 **THETIC PRODUCTS OF SELECT AGENTS AND**
 13 **TOXINS.**

14 Section 351A(a)(1) of the Public Health Service Act
 15 (42 U.S.C. 262a(a)(1)) is amended by adding at the end
 16 the following:

17 “(C) *INCLUSIONS.*—

18 “(i) *IN GENERAL.*—The following shall
 19 be considered to be a biological agent or
 20 toxin included on the list under this para-
 21 graph:

22 “(I) Any biological agent that in-
 23 corporates nucleic acids coding for a
 24 virulence factor from a listed agent or
 25 toxin.

1 “(II) *Any biological agent or*
2 *toxin that is genetically homologous to*
3 *a listed agent or toxin with respect to*
4 *nucleotides coding for virulence factors*
5 *or toxicity.*

6 “(III) *Any biological agent or*
7 *toxin that is synthetically derived with*
8 *virulence or toxicity characteristics of*
9 *a listed agent or toxin.*

10 “(IV) *Any nucleic acid that en-*
11 *codes for components contributing to*
12 *pathogenicity, transmissibility, or tox-*
13 *icity of a listed agent or toxin.*

14 “(ii) *EXEMPTIONS.—The Secretary*
15 *may exempt from inclusion on the list*
16 *under this paragraph any biological agent,*
17 *toxin, or nucleic acid described in clause*
18 *(i), if such agent, toxin, or nucleic acid does*
19 *not meet the criteria under subparagraph*
20 *(B).”.*

21 **SEC. 402. ESTABLISHMENT OF NO-FAULT REPORTING SYS-**

22 **TEM.**

23 *Title III of the Public Health Service Act is amended*
24 *by inserting after section 351A (42 U.S.C. 262a) the fol-*
25 *lowing:*

1 **“SEC. 351B. NO-FAULT REPORTING SYSTEM.**

2 “(a) *DEFINITIONS.*—*In this section:*

3 “(1) *The term ‘listed agents and toxins’ has the*
4 *meaning given the term in section 351A(l).*

5 “(2) *The term ‘reporting system’ means the re-*
6 *porting system established under subsection (b)(1).*

7 “(b) *ESTABLISHMENT.*—

8 “(1) *IN GENERAL.*—*Not later than 3 years after*
9 *the date of enactment of the Pandemic and All-Haz-*
10 *ards Preparedness and Response Act, the Secretary*
11 *shall establish a confidential, anonymous, voluntary,*
12 *no-fault reporting system related to accidents, near-*
13 *accidents, or other safety incidents involving biologi-*
14 *cal agents and toxins, in order to support continuous*
15 *improvement and sharing of lessons learned related to*
16 *such incidents.*

17 “(2) *AVAILABILITY.*—*The ability to submit re-*
18 *ports on a voluntary basis to the reporting system*
19 *shall be made available to individuals affiliated with*
20 *laboratories located in the United States, or at feder-*
21 *ally funded entities outside the United States, that*
22 *conduct research involving biological agents and tox-*
23 *ins.*

24 “(3) *DATA.*—*Not later than 2 years after the*
25 *date of enactment of the Pandemic and All-Hazards*
26 *Preparedness and Response Act, the Secretary shall*

1 *publish a notice in the Federal Register on plans for*
2 *the reporting system, including—*

3 *“(A) data elements that will be included in*
4 *the submission of reports;*

5 *“(B) procedures and processes for the sub-*
6 *mission of reports;*

7 *“(C) criteria for incidents that may be re-*
8 *ported to such system; and*

9 *“(D) procedures for privacy and*
10 *anonymization.*

11 *“(4) PROTOTYPING AND TESTING.—The Sec-*
12 *retary shall test and prototype the reporting system*
13 *for not less than 1 year before finalizing the reporting*
14 *system.*

15 *“(5) EXTERNAL FEEDBACK.—The Secretary shall*
16 *seek feedback on development of the reporting system*
17 *from external stakeholders, including prior to publica-*
18 *tion of the information under paragraph (3) and*
19 *prior to introduction of prototypes and finalization of*
20 *such system under paragraph (4).*

21 *“(c) FOIA.—*

22 *“(1) IN GENERAL.—Information submitted to, or*
23 *derived from, the reporting system shall be exempt*
24 *from disclosure under section 552 of title 5, United*
25 *States Code.*

1 “(2) *APPLICABILITY.*—*For purposes of para-*
2 *graph (1), this section shall be considered a statute*
3 *described in section 552(b)(3)(B) of title 5, United*
4 *States Code.*

5 “(d) *PROHIBITION ON USE AS EVIDENCE.*—*Informa-*
6 *tion submitted to, or derived from, the reporting system*
7 *shall not be used in any Federal or State enforcement action*
8 *or criminal prosecution.*

9 “(e) *PRIVACY; DISCIPLINARY ACTION FOR UNAUTHOR-*
10 *IZED DISCLOSURE.*—*An individual or entity that submits*
11 *information to the reporting system under subsection (b)*
12 *shall not be required to provide their name.*

13 “(f) *RELATIONSHIP TO OTHER REPORTING SYS-*
14 *TEMS.*—*The voluntary reporting system established under*
15 *this section shall supplement, and not supplant, any other*
16 *requirements to submit reports under any other reporting*
17 *system.”.*

18 **SEC. 403. EVALUATION OF THE FEDERAL SELECT AGENT**

19 **PROGRAM AND RELATED POLICIES.**

20 “(a) *IN GENERAL.*—*Not later than 4 years after the*
21 *date of enactment of this Act, the National Science Advisory*
22 *Board for Biosecurity (referred to in this section as the*
23 *“Board”)* established pursuant to section 404O of the Public
24 *Health Service Act (42 U.S.C. 283r) shall be charged with*
25 *assessing the framework for biosafety and biosecurity over-*

1 *sight, particularly with respect to mitigating risks to the*
2 *United States population with respect to biological threats.*
3 *The findings of the Board shall address scientific advance-*
4 *ments and integration of the Federal Select Agent Program*
5 *and other related Federal policies and frameworks for bio-*
6 *safety and biosecurity. The findings of the Board shall be*
7 *transmitted to the President.*

8 (b) *FRAMEWORK.*—

9 (1) *IN GENERAL.*—*The recommendations devel-*
10 *oped under subsection (a) shall include a proposed*
11 *framework for an integrated approach to the oversight*
12 *of biological research that raises significant biosafety*
13 *and biosecurity concerns, which may include pro-*
14 *posals to harmonize and modernize relevant Federal*
15 *policies such as the following:*

16 (A) *The Federal Select Agent Program.*

17 (B) *Federal policies relating to dual-use re-*
18 *search of concern.*

19 (C) *Federal policies related to federally*
20 *funded research involving enhanced pathogens of*
21 *pandemic potential.*

22 (D) *The Biosafety in Microbiological and*
23 *Biomedical Laboratories Manual of the Depart-*
24 *ment of Health and Human Services, and other*
25 *related guidance documents.*

1 (E) *The Guidelines for Research Involving*
2 *Recombinant or Synthetic Nucleic Acid Mol-*
3 *ecules of the National Institutes of Health.*

4 (2) *REQUIREMENTS FOR FRAMEWORK.—The*
5 *framework proposed under paragraph (1) shall—*

6 (A) *be developed in consultation with stake-*
7 *holders and experts from institutions of higher*
8 *education, industry, and other government agen-*
9 *cies; and*

10 (B) *make recommendations related to miti-*
11 *gating any identified risks associated with exist-*
12 *ing gaps in oversight of such research, which*
13 *may include research that does not receive Fed-*
14 *eral funding, taking into consideration any na-*
15 *tional security concerns, the potential benefits of*
16 *such research, considerations related to the re-*
17 *search community, transparency, and public*
18 *availability of information, and international*
19 *research collaboration.*

20 (c) *REORGANIZATION.—In carrying out this section,*
21 *the Board may make recommendations related to the clari-*
22 *fication of the authorities and responsibilities of relevant*
23 *Federal departments and agencies and any necessary reor-*
24 *ganization of such authorities and responsibilities among*
25 *such departments and agencies.*

1 (d) *REPORT.*—Not later than 1 year after the issuance
2 of recommendations under subsection (a), the President
3 shall submit to the Committee on Health, Education, Labor,
4 and Pensions of the Senate and the Committee on Energy
5 and Commerce of the House of Representatives, and, as ap-
6 plicable, other appropriate committees of Congress, a report
7 that describes plans to consider and implement such rec-
8 ommendations, including the identification of—

9 (1) any barriers to implementation; and

10 (2) any areas in which the President disagrees
11 with the findings or recommendations of the Board.

12 **SEC. 404. SUPPORTING RESEARCH AND LABORATORY**
13 **SURGE CAPACITY.**

14 (a) *IN GENERAL.*—The Secretary of Health and
15 Human Services (referred to in this section as the “Sec-
16 retary”) shall make awards to establish or maintain, as ap-
17 plicable, not fewer than 12 regional biocontainment labora-
18 tories, for purposes of—

19 (1) conducting biomedical research to support
20 public health and medical preparedness for, and
21 rapid response to, biological agents, including emerg-
22 ing infectious diseases;

23 (2) ensuring the availability of surge capacity
24 for purposes of responding to such biological agents;

1 (3) *supporting information sharing between, and*
2 *the dissemination of findings to, researchers and other*
3 *relevant individuals to facilitate collaboration be-*
4 *tween industry and academia; and*

5 (4) *providing, as appropriate and applicable,*
6 *technical assistance and training to researchers and*
7 *other relevant individuals to support the biomedical*
8 *research workforce in improving the management and*
9 *mitigation of safety and security risks in the conduct*
10 *of research involving such biological agents.*

11 (b) *REQUIREMENTS.—As a condition of receiving a*
12 *grant under this section, a regional biocontainment labora-*
13 *tory shall agree to—*

14 (1) *such oversight activities as the Secretary de-*
15 *termines appropriate, including periodic meetings*
16 *with relevant officials of the Department of Health*
17 *and Human Services, facility inspections, and other*
18 *activities as necessary and appropriate to ensure*
19 *compliance with the terms and conditions of such*
20 *award; and*

21 (2) *report accidents, near-accidents, or other*
22 *safety incidents involving biological agents and toxins*
23 *into the no-fault reporting system established pursu-*
24 *ant to section 351B of the Public Health Service Act,*
25 *as added by section 402.*

1 (c) *BOARD.*—*The Secretary shall establish a Board*
2 *consisting of a representative from each entity in receipt*
3 *of an award under subsection (a), which shall be headed*
4 *by an executive committee of 3 members elected upon an*
5 *affirmative vote from a majority of such representatives.*
6 *The Board shall make recommendations to the Secretary*
7 *in administering awards under this section, for purposes*
8 *of—*

9 (1) *improving the quality and consistency of ap-*
10 *plicable procedures and practices within laboratories*
11 *funded pursuant to subsection (a); and*

12 (2) *ensuring coordination, as appropriate, of fed-*
13 *erally funded activities carried out at such labora-*
14 *tories.*

15 (d) *DEFINITION.*—*In this section, the term “regional*
16 *biocontainment laboratory” means a Biosafety or Animal*
17 *Biosafety Level–3 and Level–2 facility located at an insti-*
18 *tution in the United States that is designated by the Sec-*
19 *retary to carry out the activities described in subsection (a).*

20 (e) *AUTHORIZATION OF APPROPRIATIONS.*—*To carry*
21 *out this section, there are authorized to be appropriated*
22 *\$52,000,000 for each of fiscal years 2024 through 2028.*

23 (f) *ADMINISTRATIVE EXPENSES.*—*Of the amount*
24 *available to carry out this section for a fiscal year, the Sec-*
25 *retary may use not more than 5 percent for the administra-*

1 *tive expenses of carrying out this section, including expenses*
2 *related to carrying out subsection (c).*

3 (g) *REPORT TO CONGRESS.*—*Not later than 1 year*
4 *after the date of the enactment of this Act, and biannually*
5 *thereafter, the Secretary, in consultation with the heads of*
6 *applicable Federal departments and agencies shall report*
7 *to the Committee on Health, Education, Labor, and Pen-*
8 *sions of the Senate and the Committee on Energy and Com-*
9 *merce of the House of Representatives on—*

10 (1) *the activities and accomplishments of the re-*
11 *gional biocontainment laboratories;*

12 (2) *any published or disseminated research find-*
13 *ings based on research conducted in such laboratories*
14 *in the applicable year;*

15 (3) *oversight activities carried out by the Sec-*
16 *retary pursuant to subsection (b);*

17 (4) *activities undertaken by the Secretary to take*
18 *into consideration the capacity and capabilities of the*
19 *network of regional biocontainment laboratories in*
20 *activities to prepare for and respond to biological*
21 *agents, which may include leveraging such capacity*
22 *and capabilities to support the Laboratory Response*
23 *Network, as applicable and appropriate;*

24 (5) *plans for the maintenance and sustainment*
25 *of federally funded activities conducted at the regional*

1 *biocontainment laboratories, consistent with the strat-*
2 *egy required under section 2312 of the PREVENT*
3 *Pandemics Act (Public Law 117–328); and*

4 *(6) activities undertaken by the Secretary to co-*
5 *ordinate with the heads of other relevant Federal de-*
6 *partments and agencies to ensure that work carried*
7 *out by each such facility on behalf of the Secretary*
8 *and such other relevant heads is prioritized, is com-*
9 *plementary to the work carried out by other such fa-*
10 *cilities and other relevant federally funded activities,*
11 *and avoids unnecessary duplication.*

12 **SEC. 405. GENE SYNTHESIS.**

13 *(a) GUIDANCE.—Not later than 1 year after the date*
14 *of enactment of this Act, the Secretary of Health and*
15 *Human Services (referred to in this section as the “Sec-*
16 *retary”)* shall update the Screening Framework Guidance
17 *for Providers of Synthetic Double-Stranded DNA to account*
18 *for scientific and technological advancements with respect*
19 *to mitigating the risk of unauthorized individuals or indi-*
20 *viduals with malicious intent using nucleic acid synthesis*
21 *technologies to obtain biological agents or toxins of concern.*

22 *Such guidance shall include recommendations related to—*

23 *(1) screening for sequences that the Secretary de-*
24 *termines may contribute to toxicity, pathogenicity, or*
25 *virulence;*

1 (2) *screening and verification of the identity and*
2 *legitimacy of customers;*

3 (3) *the identification, evaluation, and use of ap-*
4 *propriate software or other tools to enable the screen-*
5 *ing described in paragraphs (1) and (2);*

6 (4) *ensuring nucleic acid synthesis activities are*
7 *carried out in compliance with existing regulations*
8 *under part 73 of title 42, Code of Federal Regula-*
9 *tions, part 331 of title 7, Code of Federal Regulations,*
10 *part 121 of title 9, Code of Federal Regulations, and*
11 *part 774 of title 15, Code of Federal Regulations (or*
12 *successor regulations);*

13 (5) *implementing appropriate safeguards, which*
14 *may include the use of software or other tools, in gene*
15 *synthesis equipment to facilitate screening of nucleic*
16 *acid sequences and, as applicable, customers;*

17 (6) *maintaining records of customer orders,*
18 *metadata, and screening system or protocol perform-*
19 *ance in specified formats, which may include stand-*
20 *ardized machine-readable and interoperable data for-*
21 *mats; and*

22 (7) *other recommendations as determined appro-*
23 *priate by the Secretary.*

24 (b) *SEQUENCES OF CONCERN.—The Secretary shall*
25 *maintain a public docket to solicit recommendations on po-*

1 *tential sequences of concern and, in consultation with other*
2 *Federal departments and agencies and non-Federal experts,*
3 *as appropriate, review and update, on a regular basis, a*
4 *list of sequences of concern to facilitate screening under sub-*
5 *section (a)(1).*

6 (c) *LANDSCAPE REVIEW.*—*The Secretary, in coordina-*
7 *tion with other Federal departments and agencies, as ap-*
8 *propriate, shall conduct a landscape review of providers*
9 *and manufacturers of gene synthesis equipment, products,*
10 *software, and other tools with the purpose of understanding*
11 *the number, types, and capabilities of products and equip-*
12 *ment that exist domestically and to inform the development*
13 *of any updates to the guidance under subsection (a).*

14 (d) *TECHNICAL ASSISTANCE.*—*The Secretary, in con-*
15 *sultation with other Federal departments and agencies,*
16 *shall provide technical assistance upon request of a gene*
17 *synthesis provider, manufacturer of gene synthesis equip-*
18 *ment, or developer of software or other screening tools to*
19 *support implementation of the recommendations included*
20 *in the guidance under subsection (a).*

21 (e) *DEFINITIONS.*—*For purposes of this section:*

22 (1) *The term “gene synthesis equipment” means*
23 *equipment needed to produce gene synthesis products.*

24 (2) *The term “gene synthesis product”—*

1 (A) means custom single-stranded or double-
2 stranded DNA, or single-stranded or double-
3 stranded RNA, which has been chemically or
4 enzymatically synthesized or otherwise manufac-
5 tured de novo and is of a length exceeding the
6 screening threshold, as determined by the Sec-
7 retary; and

8 (B) does not include—

9 (i) base chemical subunits, such as—

10 (I) individual nucleotides or
11 nucleosides; or

12 (II) oligonucleotides shorter than
13 such screening threshold as is deter-
14 mined by the Secretary;

15 (ii) by-products generated during se-
16 quencing that are not useful for assembly or
17 cloning, as determined by the Secretary; or

18 (iii) products generated from cloning
19 or assembling of existing gene or gene frag-
20 ment material, in circumstances in which
21 the gene synthesis provider has no access to
22 or notice of the sequence design, as deter-
23 mined by the Secretary.

24 (3) The term “gene synthesis provider” means an
25 entity that synthesizes and distributes gene synthesis

1 *products, including bacteria, viruses, or fungi con-*
 2 *taining recombinant or synthetic nucleic acid mol-*
 3 *ecules, for delivery to a customer.*

4 (4) *The term “manufacturers of gene synthesis*
 5 *equipment” means an entity that produces and sells*
 6 *equipment for synthesizing gene synthesis products.*

7 **SEC. 406. LIMITATION RELATED TO COUNTRIES OF CON-**
 8 **CERN CONDUCTING CERTAIN RESEARCH.**

9 *Section 2315(c) of the PREVENT Pandemics Act*
 10 *(Public Law 117–328) is amended—*

11 (1) *in paragraph (1)—*

12 (A) *by inserting “that may reasonably be*
 13 *anticipated to involve the creation, transfer, and*
 14 *use of enhanced pathogens of pandemic potential*
 15 *or biological agents or toxins listed pursuant to*
 16 *section 351A(a)(1) if such research is” after “not*
 17 *fund research”; and*

18 (B) *by striking “, involving pathogens of*
 19 *pandemic potential” and all that follows through*
 20 *the period at the end and inserting a period;*

21 (2) *in paragraph (2)—*

22 (A) *in the heading, by striking “CONDI-*
 23 *TIONS FOR LISTING OR SUSPENDING PROHIBI-*
 24 *TION” and inserting “LIMITATIONS”; and*

1 (B) in the matter preceding subparagraph

2 (A)—

3 (i) by striking “The Secretary” and

4 inserting “Beginning 5 years after an ini-

5 tial determination of a country of concern

6 pursuant to paragraph (1), the Director of

7 National Intelligence or the Secretary”; and

8 (ii) by inserting “with respect to such

9 country of concern” after “paragraph (1)”;
10 and

11 (3) by adding at the end the following:

12 “(3) CLARIFICATION.—

13 “(A) IN GENERAL.—The requirement of

14 paragraph (1) may be waived by the President

15 for the duration of the initial response to an out-

16 break of a novel emerging infectious disease if

17 the President determines that such requirement

18 impedes the ability of the Federal Government to

19 immediately respond to such outbreak.

20 “(B) NOTIFICATION.—The President shall

21 notify Congress not later than 48 hours after ex-

22 ercising the waiver under subparagraph (A), and

23 shall provide updates to Congress related to the

24 use of such waiver every 15 days thereafter.”.

1 **SEC. 407. ASSESSMENT OF ARTIFICIAL INTELLIGENCE**
2 **THREATS TO HEALTH SECURITY.**

3 (a) *IN GENERAL.*—Not later than 45 days after the
4 date of enactment of this Act, the Secretary of Health and
5 Human Services (referred to in this section as the “Sec-
6 retary”) shall seek to enter into a contract with the Na-
7 tional Academies of Sciences, Engineering, and Medicine
8 (referred to in this section as the “National Academies”)
9 to conduct a study assessing the potential vulnerabilities
10 to health security presented by the current or prospective
11 use or misuse of artificial intelligence, including with re-
12 spect to open-source artificial intelligence models, such as
13 large language models.

14 (b) *INCLUSIONS.*—The study conducted pursuant to the
15 contract under subsection (a) shall include—

16 (1) *an assessment of the potential vulnerabilities*
17 *posed by technical advancements in artificial intel-*
18 *ligence to health security, including any risks related*
19 *to the development of, enhancement of, or protection*
20 *from, chemical, biological, radiological, or nuclear*
21 *threats;*

22 (2) *a description of roles, responsibilities, and*
23 *capabilities of agencies and offices of the Department*
24 *of Health and Human Services, and, as applicable*
25 *and appropriate, other Federal departments and*

1 *agencies, with respect to the identification and miti-*
2 *gation of such potential vulnerabilities;*

3 *(3) a summary of any ongoing Federal activities*
4 *related to the identification, understanding, and miti-*
5 *gation of such potential risks;*

6 *(4) the identification of any potential gaps,*
7 *whether current or anticipated, related to such roles,*
8 *responsibilities, and capabilities; and*

9 *(5) recommendations to improve Federal efforts*
10 *to identify, prepare for, and mitigate such potential*
11 *vulnerabilities.*

12 *(c) REPORTS.—*

13 *(1) NATIONAL ACADEMIES REPORT.—Not later*
14 *than 2 years after the date of the contract under sub-*
15 *section (a), the National Academies shall submit to*
16 *the Committee on Health, Education, Labor, and*
17 *Pensions of the Senate and the Committee on Energy*
18 *and Commerce of the House of Representatives a re-*
19 *port on the study conducted pursuant to subsection*
20 *(a).*

21 *(2) HHS REPORT.—Not later than 1 year after*
22 *the issuance of the report required under paragraph*
23 *(1), the Secretary shall submit to the Committee on*
24 *Health, Education, Labor, and Pensions of the Senate*
25 *and the Committee on Energy and Commerce of the*

1 *House of Representatives a report detailing actions*
 2 *taken to mitigate and monitor risks to health security*
 3 *posed by misuse of artificial intelligence, as detailed*
 4 *in the report under paragraph (1).*

5 **TITLE V—PREVENTING DRUG**
 6 **SHORTAGES**

7 **SEC. 501. IMPROVING NOTIFICATION PROCEDURES IN CASE**
 8 **OF INCREASED DEMAND FOR CRITICAL**
 9 **DRUGS.**

10 *(a) IN GENERAL.—Section 506C of the Federal Food,*
 11 *Drug, and Cosmetic Act (21 U.S.C. 356c) is amended—*

12 *(1) in the section heading, by striking “DIS-*
 13 *CONTINUANCE OR INTERRUPTION IN THE PRO-*
 14 *DUCTION OF LIFE-SAVING DRUGS” and inserting*
 15 *“NOTIFICATION OF ISSUES AFFECTING DOMES-*
 16 *TIC SUPPLY OF CRITICAL DRUGS”;*

17 *(2) by striking subsections (a), (b), and (c), and*
 18 *inserting the following:*

19 *“(a) NOTIFICATION REQUIRED.—*

20 *“(1) IN GENERAL.—A manufacturer of a covered*
 21 *drug shall notify the Secretary, in accordance with*
 22 *subsection (b), of—*

23 *“(A)(i) a permanent discontinuance in the*
 24 *manufacture of the drug or an interruption of*
 25 *the manufacture of the drug that is likely to lead*

1 to a meaningful disruption in the supply of such
2 drug in the United States;

3 “(ii) a permanent discontinuance in the
4 manufacture of an active pharmaceutical ingre-
5 dient of such drug, or an interruption in the
6 manufacture of an active pharmaceutical ingre-
7 dient of such drug that is likely to lead to a
8 meaningful disruption in the supply of the active
9 pharmaceutical ingredient of such drug; or

10 “(iii) any other circumstance, such as an
11 increase in demand or export restriction, that is
12 likely to leave the manufacturer unable to meet
13 demand for the drug without a meaningful short-
14 fall or delay; and

15 “(B) the reasons for such discontinuance,
16 interruption, or other circumstance, if known.

17 “(2) CONTENTS.—Notification under this sub-
18 section with respect to a covered drug shall include—

19 “(A) with respect to the reasons for the dis-
20 continuation, interruption, or other circumstance
21 described in paragraph (1)(A)(iii), if an active
22 pharmaceutical ingredient is a reason for, or
23 risk factor in, such discontinuation, interrup-
24 tion, or other circumstance, the source of the ac-
25 tive pharmaceutical ingredient and any alter-

1 *native sources for the active pharmaceutical in-*
2 *redient known to the manufacturer;*

3 “(B) *whether any associated device used for*
4 *preparation or administration included in the*
5 *drug is a reason for, or a risk factor in, such dis-*
6 *continuation, interruption, or other circumstance*
7 *described in paragraph (1)(A)(iii);*

8 “(C) *the expected duration of the interrup-*
9 *tion; and*

10 “(D) *such other information as the Sec-*
11 *retary may require.*

12 “(b) *TIMING.—A notice required under subsection (a)*
13 *shall be submitted to the Secretary—*

14 “(1) *at least 6 months prior to the date of the*
15 *discontinuance or interruption;*

16 “(2) *in the case of such a notice with respect to*
17 *a circumstance described in subsection (a)(1)(A)(iii),*
18 *as soon as practicable, or not later than 10 business*
19 *days after the onset of the circumstance; or*

20 “(3) *if compliance with paragraph (1) or (2) is*
21 *not possible, as soon as practicable.*

22 “(c) *DISTRIBUTION.—To the maximum extent prac-*
23 *ticable, the Secretary shall distribute, through such means*
24 *as the Secretary determines appropriate, information on*
25 *the discontinuance or interruption of the manufacture of,*

1 *or other circumstance described in subsection (a)(1)(A)(iii)*
 2 *that is likely to lead to a shortage or meaningful disruption*
 3 *in the supply of, covered drugs to appropriate organiza-*
 4 *tions, including physician, health provider, and patient or-*
 5 *ganizations, as described in section 506E.”;*

6 (3) *in subsection (g), in the matter preceding*
 7 *paragraph (1), by striking “drug described in sub-*
 8 *section (a)” and inserting “covered drug”; and*

9 (4) *in subsection (j), by striking “drug described*
 10 *in subsection (a)” and inserting “covered drug”.*

11 (b) *DEFINITIONS.—Paragraph (1) of section 506C(h)*
 12 *of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.*
 13 *356c(h)) is amended to read as follows:*

14 “(1) *the term ‘covered drug’ means a drug that*
 15 *is intended for human use and that—*

16 “(A) *is—*

17 “(i) *life-supporting;*

18 “(ii) *life-sustaining; or*

19 “(iii) *intended for use in the preven-*
 20 *tion or treatment of a debilitating disease*
 21 *or condition, including any such drug used*
 22 *in emergency medical care or during sur-*
 23 *gery or any such drug that is critical to the*
 24 *public health during a public health emer-*

1 *gency declared by the Secretary under sec-*
2 *tion 319 of the Public Health Service Act;*

3 *“(B) is not a radio pharmaceutical drug*
4 *product or any other product as designated by*
5 *the Secretary; and*

6 *“(C) is not a biological product (as defined*
7 *in section 351(i) of the Public Health Service*
8 *Act), unless otherwise provided by the Secretary*
9 *in the regulations promulgated under subsection*
10 *(i);”.*

11 **SEC. 502. REPORTING ON SUPPLY CHAINS.**

12 *Section 510(j)(3)(A) of the Federal Food, Drug, and*
13 *Cosmetic Act (21 U.S.C. 360(j)(3)(A)) is amended—*

14 *(1) by inserting “, and the names and unique fa-*
15 *cility identifiers of the manufacturers of the active*
16 *pharmaceutical ingredients such person used for the*
17 *manufacture, preparation, propagation,*
18 *compounding, or processing of such drug, and the*
19 *amount of such drug manufactured, prepared, propa-*
20 *gated, compounded, or processed using each such ac-*
21 *tive pharmaceutical ingredient from each such manu-*
22 *facturer” before the period at the end of the first sen-*
23 *tence; and*

24 *(2) by inserting after the first sentence the fol-*
25 *lowing: “In addition to the reporting required under*

1 *the preceding sentence, the Secretary may receive vol-*
2 *untary submissions of such information at more fre-*
3 *quent intervals.”.*

4 **SEC. 503. REPORTING ON USE OF NEW AUTHORITIES AND**
5 **REQUIREMENTS WITH RESPECT TO DRUG**
6 **SHORTAGES.**

7 *Not later than 90 days after the date of enactment of*
8 *this Act, the Secretary of Health and Human Services (re-*
9 *ferred to in this section as the “Secretary”) shall report to*
10 *the Committee on Health, Education, Labor, and Pensions*
11 *of the Senate and the Committee on Energy and Commerce*
12 *of the House of Representatives on—*

13 (1) *the extent to which the Secretary has imple-*
14 *mented the authorities and requirements under sec-*
15 *tions 506C(g), 506C(j), 506E(d), 510(j)(3), and*
16 *704(b)(2) (21 U.S.C. 356c(g), 356c(j), 356e(d),*
17 *360(j)(3), 374(b)(2)) of the Federal Food, Drug, and*
18 *Cosmetic Act, as amended by sections 3111 and 3112*
19 *of the Coronavirus Aid, Relief, and Economic Secu-*
20 *urity Act (Public Law 116–136), including—*

21 (A) *specific examples of uses of such au-*
22 *thorities and requirements; and*

23 (B) *an assessment of the extent to which*
24 *such authorities and requirements have helped*
25 *mitigate drug shortages; and*

1 (2) *the status of the guidance documents that the*
2 *Secretary intends to issue with respect to reporting*
3 *and risk management plan requirements applicable to*
4 *manufacturers of drugs and active pharmaceutical in-*
5 *gredients, pursuant to the amendments made to sec-*
6 *tion 506C of the Federal Food, Drug, and Cosmetic*
7 *Act (21 U.S.C. 356c) by subsections (a) and (b) of*
8 *section 3112 of the Coronavirus Aid, Relief, and Eco-*
9 *nomic Security Act (Public Law 116–136).*

10 **TITLE VI—ADDITIONAL REAU-**
11 **THORIZATIONS AND TECH-**
12 **NICAL AMENDMENTS**

13 **SEC. 601. MEDICAL COUNTERMEASURE PRIORITY REVIEW**
14 **VOUCHER.**

15 *Section 565A(g) of the Federal Food, Drug, and Cos-*
16 *metic Act (21 U.S.C. 360bbb–4a) is amended by striking*
17 *“2023” and inserting “2028”.*

18 **SEC. 602. EPIDEMIC INTELLIGENCE SERVICE LOAN REPAY-**
19 **MENT PROGRAM.**

20 *Section 317F(c)(2) of the Public Health Service Act*
21 *(42 U.S.C. 247b–7(c)(2)) is amended by striking “2019*
22 *through 2023” and inserting “2024 through 2028”.*

1 **SEC. 603. VACCINE TRACKING AND DISTRIBUTION.**

2 *Section 319A(e) of the Public Health Service Act (42*
3 *U.S.C. 247d-1(e)) is amended by striking “2019 through*
4 *2023” and inserting “2024 through 2028”.*

5 **SEC. 604. REGIONAL HEALTH CARE EMERGENCY PRE-**
6 **PAREDNESS AND RESPONSE SYSTEMS.**

7 *Section 319C-3(e)(2) of the Public Health Service Act*
8 *(42 U.S.C. 247d-3c(e)(2)) is amended by striking “2023”*
9 *and inserting “2028”.*

10 **SEC. 605. EMERGENCY SYSTEM FOR ADVANCE REGISTRA-**
11 **TION OF VOLUNTEER HEALTH PROFES-**
12 **SIONAL.**

13 *Section 319I(k) of the Public Health Service Act (42*
14 *U.S.C. 247d-7b(k)) is amended by striking “2019 through*
15 *2023” and inserting “2024 through 2028”.*

16 **SEC. 606. LIMITED ANTITRUST EXEMPTION.**

17 *Section 319L-1(b) of the Public Health Service Act (42*
18 *U.S.C. 247d-7f(b)) is amended by striking “at the end of*
19 *the 17-year period that begins on the date of enactment of*
20 *this Act” and inserting “on September 30, 2028”.*

21 **SEC. 607. TRAUMA CARE.**

22 *Section 1232(a) of the Public Health Service Act (42*
23 *U.S.C. 300d-32(a)) is amended by striking “\$24,000,000*
24 *for each of fiscal years 2023 through 2027” and inserting*
25 *“\$39,000,000 for each of fiscal years 2024 through 2028”.*

1 **SEC. 608. MILITARY AND CIVILIAN PARTNERSHIP FOR**
2 **TRAUMA READINESS.**

3 *Section 1291(g) of the Public Health Service Act (42*
4 *U.S.C. 300d–91(g)) is amended by striking “2019 through*
5 *2023” and inserting “2024 through 2028”.*

6 **SEC. 609. NATIONAL DISASTER MEDICAL SYSTEM.**

7 *Section 2812 of the Public Health Service Act (42*
8 *U.S.C. 300hh–11) is amended—*

9 *(1) in subsection (c)(4)(B), by striking “2023”*
10 *and inserting “2028”; and*

11 *(2) in subsection (g), by striking “\$57,400,000*
12 *for each of fiscal years 2019 through 2023” and in-*
13 *serting “\$65,900,000 for each of fiscal years 2024*
14 *through 2028”.*

15 **SEC. 610. VOLUNTEER MEDICAL RESERVE CORPS.**

16 *Section 2813(i) of the Public Health Service Act (42*
17 *U.S.C. 300hh–15(i)) is amended by striking “2019 through*
18 *2023” and inserting “2024 through 2028”.*

19 **SEC. 611. EPIDEMIOLOGY-LABORATORY CAPACITY GRANTS.**

20 *Section 2821(b) of the Public Health Service Act (42*
21 *U.S.C. 300hh–31(b)) is amended, in the matter preceding*
22 *paragraph (1), by striking “2019 through 2023” and insert-*
23 *ing “2024 through 2028”.*

1 **SEC. 612. VETERANS AFFAIRS.**

2 *Section 8117(g) of title 38, United States Code is*
3 *amended by striking “2019 through 2023” and inserting*
4 *“2024 through 2028”.*

5 **SEC. 613. TECHNICAL AMENDMENTS.**

6 *(a) Title XXI of the Public Health Service Act (42*
7 *U.S.C. 300aa–1 et seq.) is amended—*

8 *(1) in section 2105(b), by striking “, 2103, and*
9 *2104” each place it appears and inserting “and*
10 *2103”;*

11 *(2) in section 2110(b), by striking “the program”*
12 *and inserting “the Program”;*

13 *(3) in section 2111(a)—*

14 *(A) in paragraph (6), by striking “1988*
15 *for” and inserting “1988, for”; and*

16 *(B) in paragraph (10), by striking “United*
17 *States Claims Court” and inserting “United*
18 *States Court of Federal Claims”;*

19 *(4) in section 2112—*

20 *(A) in subsection (c)(6)(A), by striking*
21 *“United States Claims Courts” and inserting*
22 *“United States Court of Federal Claims”; and*

23 *(B) in subsection (f)—*

24 *(i) by striking “United States Claims*
25 *Court on” and inserting “United States*
26 *Court of Federal Claims on”; and*

1 (ii) by striking “United States Claims
2 Court’s judgment” and inserting “judgment
3 of the United States Court of Federal
4 Claims”;

5 (5) in section 2115(b)(3), by striking “subsection
6 (e)” and inserting “subsection (e)”;

7 (6) in section 2117—

8 (A) in the section heading, by striking
9 “**SUBROGRATION**” and inserting “**SUBROGA-**
10 **TION**”; and

11 (B) in subsection (a), by striking
12 “subrogated” and inserting “subrogated”; and

13 (7) in section 2127—

14 (A) in subsection (b)(1), by inserting “and
15 Prevention” before the period; and

16 (B) in subsection (c), by striking “Com-
17 mittee on Labor and Human Resources” and in-
18 serting “Committee on Health, Education,
19 Labor, and Pensions”.

20 (b) Section 319F–3 of the Public Health Service Act
21 (42 U.S.C. 247d–6d) is amended—

22 (1) in subsection (c)(5)(B)(ii)(I), by striking
23 “chapter 5” and inserting “chapter V”; and

24 (2) in subsection (i)(7)—

1 (A) by striking “321(g)(1))” and inserting
2 “321(g)(1))”; and

3 (B) by striking “321(h))” and inserting
4 “321(h))”.

5 (c) Section 319F–4 of the Public Health Service Act
6 (42 U.S.C. 247d–6e) is amended—

7 (1) in subsection (b)(1), by striking “under
8 319F–3(b)” and inserting “under section 319F–3(b);
9 and

10 (2) in subsection (d)(5), by striking “under sub-
11 section (a) the Secretary determines that a covered in-
12 dividual qualifies for compensation” and inserting “a
13 covered individual is determined under subsection (a)
14 to be eligible for compensation under this section”.

15 (d) Section 319I of the Public Health Service Act (42
16 U.S.C. 247d–7b) is amended, in the section heading, by
17 striking “**PROFESSIONAL**” and inserting “**PROFES-**
18 **SIONALS**”.

19 (e) Part C of title II of the Public Health Service Act
20 (42 U.S.C. 239 et seq.) is amended—

21 (1) in section 261(a)(2)(A), by striking “speciali-
22 ties” and inserting “specialties”;

23 (2) in section 265(c)(5), by striking “involves”
24 and inserting “involved”;

1 (3) in section 266(b)(3)(B)(ii), by striking “to
2 with respect to an eligible” and inserting “with re-
3 spect to an eligible”; and

4 (4) in section 267(b), by striking “such Act” and
5 inserting “such part”.

6 (f) Section 351A(e)(7)(B)(ii) is amended by striking
7 “judical” and inserting “judicial”.

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118TH CONGRESS
1ST Session

S. 2333

A BILL

To reauthorize certain programs under the Public Health Service Act with respect to public health security and all-hazards preparedness and response, and for other purposes.

SEPTEMBER 6, 2023

Reported with an amendment